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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2020–0253]

Advanced Manufacturing Technologies Subtask 2A

AGENCY: Nuclear Regulatory Commission.

ACTION: Final report; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing the final document entitled, ''Implementation of Quality Assurance Criteria and 10 CFR 50.59 for Nuclear Power Plant Components Produced Using Advanced Manufacturing Technologies.''

DATES: This final report is available on July 23, 2021.

ADDRESSES: Please refer to Docket ID NRC–2020–0253 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0253. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
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- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Isaac Anchondo-Lopez, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 817–200–1152; email: *Isaac.Anchondo-Lopez@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The NRC considers Advanced Manufacturing Technologies (AMTs) to consist of material processing and component fabrication methods that have not been traditionally used in the U.S. nuclear industry and have not yet received NRC approval through NRC-endorsed codes and standards or the approval of an industry submittal. There are several regulatory paths available to a licensee for utilizing an AMT in a nuclear application, including: (1) Development of a code or standard that can be incorporated by reference in § 50.55a of chapter I of title 10 of the *Code of Federal Regulations* (10 CFR); (2) selection of an unregulated in service application; (3) submission of generic technical reports or plant-specific submittals for NRC approval; or (4) implementation of the 10 CFR 50.59, ''Changes, tests and experiments,'' 10 CFR 70.72, ''Facility changes and change process,'' or 10 CFR 72.48, ''Changes, tests, and experiments'' processes. The document addresses the processes, consistent with the QA requirements in appendix B to 10 CFR part 50 and in accordance with 10 CFR 50.59, in order to support the staff's performance of potential inspections of a licensee's implementation of these requirements for AMT-fabricated components.

II. Congressional Review Act

This action is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

III. Implementation

The staff has added Appendix A, ''Disposition of Public Comments,'' to the final document to inform the reader how public comments were dispositioned. The Division of New and Renewed Licenses of the Office of Nuclear Reactor Regulation will transmit the final version of the document (ADAMS Accession Number ML21155A043) to each of the NRC Regional Offices via a memo to be issued concurrently with publication of this **Federal Register** notification.

Dated: July 19, 2021.

For the Nuclear Regulatory Commission.

Anna H. Bradford,

Director, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2021–15658 Filed 7–22–21; 8:45 am]

BILLING CODE 7590–01–P

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Docket No. R–1753]

RIN 7100–AG17

Regulation D: Reserve Requirements of Depository Institutions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (''Board'') is amending Regulation D, Reserve Requirements of Depository Institutions to revise the rate of interest paid on balances maintained to satisfy reserve balance requirements (''IORR'') and the rate of interest paid on excess balances (''IOER'') maintained at Federal Reserve Banks by or on behalf of eligible institutions. The final amendments specify that IORR is 0.15 percent and IOER is 0.15 percent, a 0.05 percentage point increase from their prior levels. The amendments are intended to enhance the role of IORR and IOER in maintaining the Federal funds rate in the target range established by the Federal Open Market Committee (''FOMC'' or ''Committee'').

DATES:

Effective date: The amendments to part 204 (Regulation D) are effective July 23, 2021.

Applicability date: The IORR and IOER rate changes were applicable on June 17, 2021.

FOR FURTHER INFORMATION CONTACT: Sophia H. Allison, Senior Special Counsel (202–452–3565), Legal Division, or Francis Martinez, Lead Financial Institution & Policy Analyst (202–245–4217), or Laura Lipscomb, Deputy Associate Director (202–834–2979), Division of Monetary Affairs; for users of Telecommunications Device for the Deaf (TDD) only, contact 202–263–4869; Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

For monetary policy purposes, section 19 of the Federal Reserve Act (''Act'') imposes reserve requirements on certain types of deposits and other liabilities of depository institutions.[1] Regulation D, which implements section 19 of the Act, requires that a depository institution meet reserve requirements by holding cash in its vault, or if vault cash is insufficient, by maintaining a balance in an account at a Federal Reserve Bank (''Reserve Bank'').[2] Section 19 also provides that balances maintained by or on behalf of certain institutions in an account at a Reserve Bank may receive earnings to be paid by the Reserve Bank at least once each quarter, at a rate or rates not to exceed the general level of short-term interest rates.[3] Institutions that are eligible to receive earnings on their balances held at Reserve Banks (''eligible institutions'') include depository institutions and certain other institutions.[4] Section 19 also provides that the Board may prescribe regulations concerning the payment of earnings on balances at a Reserve Bank.[5] Prior to these amendments, Regulation D specified a rate of 0.10 percent for both IORR and IOER.[6]

II. Amendments to IORR and IOER

The Board is amending § 204.10(b)(5) of Regulation D to specify that IORR is 0.15 percent and IOER is 0.15 percent. The amendments represent a 0.05 percentage point increase in IORR and IOER. This decision was announced on June 16, 2021, with an effective date of June 17, 2021, in the Federal Reserve Implementation Note that accompanied the FOMC's statement on June 16, 2021. The FOMC statement stated that the Committee decided to maintain the target range for the federal funds rate at 0 to ¼ percent.

A Federal Reserve Implementation note stated:

> The Board of Governors of the Federal Reserve System voted unanimously to set the interest rate paid on required and excess reserve balances at 0.15 percent, effective June 17, 2021 Setting the interest rate paid on required and excess reserve balances 15 basis points above the bottom of the target range for the federal funds rate is intended to foster trading in the federal funds market at rates well within the Federal Open Market Committee's target range and to support the smooth functioning of short-term funding markets.

As a result, the Board is amending § 204.10(b)(5) of Regulation D to change IORR to 0.15 percent and IOER to 0.15 percent.

III. Administrative Procedure Act

In general, the Administrative Procedure Act (''APA'')[7] imposes three principal requirements when an agency promulgates legislative rules (rules made pursuant to Congressionally-delegated authority): (1) Publication with adequate notice of a proposed rule; (2) followed by a meaningful opportunity for the public to comment on the rule's content; and (3) publication of the final rule not less than 30 days before its effective date. The APA provides that notice and comment procedures do not apply if the agency for good cause finds them to be ''unnecessary, impracticable, or contrary to the public interest.''[8] Section 553(d) of the APA also provides that publication at least 30 days prior to a rule's effective date is not required for (1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretive rules and statements of policy; or (3) a rule for which the agency finds good cause for shortened notice and publishes its reasoning with the rule.[9]

The Board has determined that good cause exists for finding that the notice, public comment, and delayed effective date provisions of the APA are unnecessary, impracticable, or contrary to the public interest with respect to these final amendments to Regulation D. The rate changes for IORR and IOER that are reflected in the final amendments to Regulation D were made with a view towards accommodating commerce and business and with regard to their bearing upon the general credit situation of the country. Notice and public comment would prevent the Board's action from being effective as promptly as necessary in the public interest and would not otherwise serve any useful purpose. Notice, public comment, and a delayed effective date would create uncertainty about the finality and effectiveness of the Board's action and undermine the effectiveness of that action. Accordingly, the Board has determined that good cause exists to dispense with the notice, public comment, and delayed effective date procedures of the APA with respect to these final amendments to Regulation D.

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA'') does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[10] As noted previously, the Board has determined that it is unnecessary and contrary to the public interest to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (''PRA'') of 1995,[11] the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

List of Subjects in 12 CFR Part 204

Banks, Banking, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, the Board amends 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

■ 1. The authority citation for part 204 continues to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 461, 601, 611, and 3105.

■ 2. Section 204.10 is amended by revising paragraph (b)(5) to read as follows:

§ 204.10 Payment of interest on balances.

* * * * *

[1] 12 U.S.C. 461(b).

[2] 12 CFR 204.5(a)(1).

[3] 12 U.S.C. 461(b)(1)(A) & (b)(12)(A).

[4] See 12 U.S.C. 461(b)(1)(A) & (b)(12)(C); see also 12 CFR 204.2(y).

[5] See 12 U.S.C. 461(b)(12)(B).

[6] See 12 CFR 204.10(b)(5).

[7] 5 U.S.C. 551 *et seq.*

[8] 5 U.S.C. 553(b)(3)(A).

[9] 5 U.S.C. 553(d).

[10] 5 U.S.C. 603, 604.

[11] 44 U.S.C. 3506; see 5 CFR part 1320, appendix A.1.

(b) * * *

(5) The rates for IORR and IOER are:

TABLE 1 TO PARAGRAPH (b)(5)

	Rate (percent)
IORR	0.15
IOER	0.15

* * * * *

By order of the Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2021–15671 Filed 7–22–21; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–0865; Project Identifier 2010–SW–061–AD; Amendment 39–21653; AD 2021–15–06]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bell Helicopter Textron Canada Limited (now Bell Textron Canada Limited) Model 206A, 206B, 206L, 206L–1, 206L–3, and 206L–4 helicopters. This AD was prompted by a report that a certain tail rotor disc assembly, sold as an alternate part, does not conform to the approved configuration. This AD requires determining if an affected part is installed (by doing a maintenance records check or inspection), and if an affected part is found, replacement with a non-affected part. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 27, 2021.

The Director of the Federal Register approved the incorporation by reference of certain documents listed in this AD as of August 27, 2021.

ADDRESSES: For service information identified in this final rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; phone: 450–437–2862 or 800–363–8023; fax: (450) 433–0272; internet: *https://www.bellcustomer.com.* You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. Service information that is incorporated by reference is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2010–0865.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2010–0865; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the Transport Canada AD, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Program Manager, Large Aircraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: (206) 231–3218; email: *kathleen.arrigotti@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bell Textron Canada Limited Model 206A, 206B, 206L, 206L–1, 206L–3, and 206L–4 helicopters. The SNPRM published in the **Federal Register** on May 7, 2021 (86 FR 24560). The SNPRM proposed to require determining if an affected part is installed (by doing a maintenance records check or inspection), and if an affected part is found, replacement with a non-affected part. The SNPRM also revised the format, rearranged certain paragraphs, converted a certain table to paragraph format, and removed certain language. The SNPRM was prompted by a significant amount of time elapsing since the notice of proposed rulemaking (NPRM) (75 FR 52914, August 30, 2010) was issued, requiring the FAA to reopen the comment period to allow the public a chance to comment on the proposed actions.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, issued Canadian AD CF–2010–07, dated February 24, 2010 (Canadian AD CF–2010–07), to correct an unsafe condition for certain Bell Helicopter Textron Canada Limited (now Bell Textron Canada Limited) Model 206A, 206B, 206L, 206L–1, 206L–3, and 206L–4 helicopters. TCCA advises that a certain tail rotor disc assembly, sold through Bell Helicopter Spares beginning March 2009, as an alternate, does not conform to the approved configuration. TCCA stated operating a helicopter with the affected tail rotor disc assembly could result in loss of control of the helicopter.

Accordingly, the Canadian AD requires determining if an affected part is installed, and if an affected part is found, replacement with a non-affected part.

Discussion of Final Airworthiness Directive Comments

The FAA received a comment from one commenter, Bell Textron Canada Limited. The following presents the comment received on the SNPRM and the FAA's response to the comment.

Request To Add a Statement for Operators That Already Complied With the Actions

Bell Textron Canada Limited requested that the FAA add a statement to the effect that if the actions in Bell Helicopter Alert Service Bulletin 206–09–123, Revision A, dated June 10, 2009; or Bell Helicopter Alert Service Bulletin 206L–09–157, Revision A, dated June 10, 2009; have already been accomplished then the intent of the AD is met and no further action is required. The commenter stated that many operators will have already complied with the intent of the proposed AD since the service information was released in 2009.

The FAA acknowledges the commenter's request and agrees to clarify. Paragraph (g) of this AD requires accomplishing actions using Bell Helicopter Alert Service Bulletin 206–09–123, Revision A, dated June 10, 2009; or Bell Helicopter Alert Service Bulletin 206L–09–157, Revision A, dated June 10, 2009. Paragraph (f) of this AD states to accomplish the required actions within the compliance times specified, ''unless already done.'' Therefore, if operators have accomplished the actions required for compliance with this AD before the effective date of this AD, no further action is necessary. The FAA has not revised this AD in this regard.

Conclusion

These helicopters have been approved by the aviation authority of Canada and

are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, TCCA, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA reviewed the relevant data, considered the comment received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following service information. This service information specifies procedures to determine if an affected part is installed, and if an affected part is found, replacement with a non-affected part. These documents are distinct since they apply to different helicopter models.

- Bell Helicopter Alert Service Bulletin 206–09–123, Revision A, dated June 10, 2009.
- Bell Helicopter Alert Service Bulletin 206L–09–157, Revision A, dated June 10, 2009.

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

Costs of Compliance

The FAA estimates that this AD affects 1,493 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$303	$388	$579,284

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–15–06 Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited): Amendment 39–21653; Docket No. FAA–2010–0865; Project Identifier 2010–SW–061–AD.

(a) Effective Date

This airworthiness directive (AD) is effective August 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) helicopters, certificated in any category:

(1) Model 206A, serial numbers 004 through 660 inclusive, and 672 through 715 inclusive;

(2) Model 206B, all serial numbers, including those converted from Model 206A;

(3) Model 206L, serial numbers 45004 through 45153 inclusive, and 46601 through 46617 inclusive;

(4) Model 206L–1, serial numbers 45154 through 45790 inclusive;

(5) Model 206L–3, serial numbers 51001 through 51612 inclusive; and

(6) Model 206L–4, all serial numbers.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 65, Tail Rotor Drive.

(e) Unsafe Condition

This AD was prompted by a report that a certain tail rotor disc assembly, sold as an alternate part, does not conform to the approved configuration. The FAA is issuing this AD to address helicopters operating with a certain tail rotor disc assembly, sold as an alternate part, that does not conform to the approved configuration, which could result in loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

Do the actions specified in paragraphs (g)(1) through (4) of this AD, in accordance with Bell Helicopter Alert Service Bulletin 206–09–123, Revision A, dated June 10, 2009; or Bell Helicopter Alert Service Bulletin 206L–09–157, Revision A, dated June 10, 2009, as applicable.

(1) Within 30 days or 100 hours time-in-service (TIS) after the effective date of this AD, whichever occurs first, review the helicopter maintenance records to determine if a disc assembly, part number (P/N) 101584–1 or –2, is installed.

(2) If, during the maintenance records review required by paragraph (g)(1) of this AD, you cannot positively determine that disc assembly P/N 101584–1 or –2 is not installed, within 30 days or 100 hours TIS after the effective date of this AD, whichever occurs first, inspect the tail rotor driveshaft system to determine if disc assembly P/N 101584–1 or –2 is installed.

(3) If, during the maintenance records review required by paragraph (g)(1) of the this AD or during the inspection required by paragraph (g)(2) of this AD, you can positively determine that a disc assembly P/N 101584–1 or –2 is not installed, before further flight, make an entry in the log book showing compliance with this AD.

(4) If, during the maintenance records review required by paragraph (g)(1) of this AD or during the inspection required by paragraph (g)(2) of this AD, you can positively determine that a disc assembly P/N 101584–1 or –2 is installed, within 30 days or 100 hours TIS after the effective date of this AD, whichever occurs first, replace disc assembly P/N 101584–1 or –2 with disc assembly P/N 32721–1.

(h) Parts Installation Prohibition

As of the effective date of this AD, do not install disc assembly P/N 101584–1 or –2.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Related Information

(1) For more information about this AD, contact Kathleen Arrigotti, Program Manager, Large Aircraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: (206) 231–3218; email: *kathleen.arrigotti@faa.gov.*

(2) The subject of this AD is addressed in Transport Canada Civil Aviation (TCCA) Canadian AD CF–2010–07, dated February 24, 2010. You may view the TCCA AD at *https://www.regulations.gov* in Docket No. FAA–2010–0865.

(k) Material Incorporated by Reference

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

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

(i) Bell Helicopter Alert Service Bulletin 206–09–123, Revision A, dated June 10, 2009.

(ii) Bell Helicopter Alert Service Bulletin 206L–09–157, Revision A, dated June 10, 2009.

(3) For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; phone: 450–437–2862 or 800–363–8023; fax: (450) 433–0272; internet: *https://www.bellcustomer.com.*

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

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

Issued on July 9, 2021.

Gaetano A. Sciortino,

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

[FR Doc. 2021–15478 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0188; Project Identifier MCAI–2020–00642–R; Amendment 39–21572; AD 2021–11–10]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. This AD was prompted by a report that damage (scorch marks) was found on an internal life raft installation that contained a half rescue kit. This AD requires identifying the part number and serial number of each half rescue kit located in the internal life raft installation and, depending on the findings, inspecting the life raft for damage, inspecting the condition of the flashlight battery, testing the flashlight battery, and replacing the life raft or flashlight battery (including the leak test) as applicable, as specified in a European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 27, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 27, 2021.

ADDRESSES: For EASA material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this material on the EASA website at *https://ad.easa.europa.eu.* For Zodiac Aerospace service information identified in this final rule, contact Safran Aerosystems—Plaisir, 61 rue Pierre Curie CS20001, 78373 Plaisir Cedex, France; telephone (33) 1 61 34 23 23; fax (33) 1 61 34 24 41; or at *https://www.safran-aerosystems.com.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0188.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0188; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kathleen Arrigotti, Program Manager, Large Aircraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218; email *kathleen.arrigotti@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2016–0028, dated February 15, 2016 (EASA AD 2016–0028) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Airbus Helicopters Model

SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters. The NPRM published in the **Federal Register** on March 23, 2021 (86 FR 15431). The NPRM was prompted by a report that damage (scorch marks) was found on an internal life raft installation that contained a half rescue kit. Investigation revealed that the damage was caused by an unsuitable folding process for the life raft, which led to compression of the flashlight battery in the half rescue kit. This compression caused an electrolyte leakage, followed by a short-circuit that damaged the internal life raft. The NPRM proposed to require identifying the part number and serial number of each half rescue kit located in the internal life raft installation and, depending on the findings, inspecting the life raft for damage, inspecting the condition of the flashlight battery, testing the flashlight battery, and replacing the life raft or flashlight battery (including the leak test) as applicable, as specified in an EASA AD.

The FAA is issuing this AD to address leakage of the flashlight battery in a half rescue kit, which could result in damage to the internal life raft, and subsequent failure of the internal life raft to deploy (for example after a ditching), which could impede or prevent safe evacuation of the occupants from the helicopter. See the MCAI for additional background information.

Discussion of Final Airworthiness Directive

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA received no comments on the NPRM or on the determination of the cost to the public.

Costs of Compliance Update

The NPRM did not include the kit cost for the on-condition action specified in paragraph (2) of EASA AD 2016–0028. The FAA has received this cost data and has updated the costs of compliance accordingly.

Conclusion

The FAA reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor changes. In the NPRM, the FAA proposed to require actions specified in EASA AD 2016–0028 through incorporation by reference, except for certain differences. The FAA has obtained approval to use this process from certain manufacturers, including Airbus Helicopters; however, the FAA has not worked with Zodiac Aerospace (which has been merged into Safran Aerosystems) for approval of this process. EASA AD 2016–0028 specifies using Zodiac Aerospace Service Bulletin SB 025–64–13, Revision 0, dated November 23, 2015 (SB 025–64–13 Rev 0) or Revision 1, dated January 19, 2016 (SB 025–64–13 Rev 1), to accomplish a certain action. In light of this, an exception has been added into this final rule to directly use SB 025–64–13 Rev 0 or SB 025–64–13 Rev 1, instead of using SB 025–64–13 Rev 0 or SB 025–64–13 Rev 1 through incorporation by reference of EASA AD 2016–0028.

The FAA has determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

EASA AD 2016–0028 specifies identifying the part number and serial number of each half rescue kit located in the internal life raft installation, inspecting the life raft for damage (scorch marks), inspecting the condition of the flashlight battery (including cracks, impacts, swelling, damage, distorted case, and the connecting wire), testing the flashlight battery (turning on the flashlight), and replacing the life raft or flashlight battery (including the leak test).

The FAA reviewed SB 025–64–13 Rev 0, which specifies procedures to visually inspect the condition of the life raft and battery, and test the battery. The FAA also reviewed SB 025–64–13 Rev 1, which specifies the same procedures as SB 025–64–13 Rev 0, except SB 025–64–13 Rev 1 corrects the serial numbers identified in the effectivity.

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

Differences Between This AD and the MCAI

Although the service information referenced in EASA AD 2016–0028 specifies to return damaged life rafts to the manufacturer, this AD does not include that requirement.

Where EASA AD 2016–0028 refers to its effective date or to January 7, 2016 (the effective date of EASA AD 2015–0242), this AD requires compliance within 3 months after the effective date of this AD.

Although the service information referenced in EASA AD 2016–0028 specifies that trained and authorized Zodiac Aerospace personnel must do the inspection of the half rescue kit, this AD does not require that Zodiac Aerospace personnel do the inspection.

Costs of Compliance

The FAA estimates that this AD affects 30 helicopters of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$3,000	$3,085	$92,550

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
7.5 work-hours × $85 per hour = $637.50	Up to $78,154	Up to $78,791.50.

According to Zodiac Aerospace, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators. The FAA does not control warranty coverage for affected operators. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–11–10 Airbus Helicopters: Amendment 39–21572; Docket No. FAA–2021–0188; Project Identifier MCAI–2020–00642–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Helicopters Model SA–365N, SA–365N1, AS–365N2, and AS 365 N3 helicopters, certificated in any category, as identified in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2016–0028, dated February 15, 2016 (EASA AD 2016–0028).

(d) Subject

Joint Aircraft System Component (JASC) Code 2564, Life Raft.

(e) Reason

This AD was prompted by a report that damage (scorch marks) was found on an internal life raft installation that contained a half rescue kit. Investigation revealed that the damage was caused by an unsuitable folding process for the life raft, which led to compression of the flashlight battery in the half rescue kit. The FAA is issuing this AD to address leakage of the flashlight battery in a half rescue kit, which could result in damage to the internal life raft, and subsequent failure of the internal life raft to deploy (for example after a ditching), which could impede or prevent safe evacuation of the occupants from the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2016–0028.

(h) Exceptions to EASA AD 2016–0028

(1) Where EASA AD 2016–0028 refers to its effective date or to January 7, 2016 (the effective date of EASA AD 2015–0242), this AD requires compliance within 3 months after the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2016–0028 does not apply to this AD.

(3) Where paragraph (2) of EASA AD 2016–0028 specifies accomplishing corrective actions in accordance with the instructions of Zodiac Aerospace SB No. 025–64–13 referred to in paragraph 3.B of Airbus Helicopters ASB AS365–25.01.63, this AD requires using Zodiac Aerospace Service Bulletin SB 025–64–13, Revision 0, dated November 23, 2015 or Revision 1, dated January 19, 2016.

(4) Although the service information referenced in EASA AD 2016–0028 specifies to return certain parts, this AD does not include that requirement.

(5) Although the service information referenced in EASA AD 2016–0028 specifies that trained and authorized Zodiac Aerospace personnel must do the inspection of the half rescue kit, this AD does not require that Zodiac Aerospace personnel do the inspection.

(i) Alternative Methods of Compliance (AMOCs)

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

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

(j) Related Information

For more information about this AD, contact Kathleen Arrigotti, Program Manager, Large Aircraft Section, International Validation Branch, Compliance & Airworthiness Division, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax (206) 231–3218; email *kathleen.arrigotti@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference

(IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(i) European Aviation Safety Agency (EASA) AD 2016–0028, dated February 15, 2016.

(ii) Zodiac Aerospace Service Bulletin SB 025–64–13, Revision 0, dated November 23, 2015.

(iii) Zodiac Aerospace Service Bulletin SB 025–64–13, Revision 1, dated January 19, 2016.

(3) For EASA AD 2016–0028, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* For Zodiac Aerospace service information, contact Safran Aerosystems—Plaisir, 61 rue Pierre Curie CS20001, 78373 Plaisir Cedex, France; telephone (33) 1 61 34 23 23; fax (33) 1 61 34 24 41; or at *https://www.safran-aerosystems.com.*

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0188.

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

Issued on June 10, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15480 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1179; Project Identifier AD–2020–00818–E; Amendment 39–21638; AD 2021–14–11]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain General Electric Company (GE) CF6–80A and CF6–80C2 model turbofan engines. This AD was prompted by an inspection by the manufacturer that revealed cracking of the high-pressure turbine (HPT) rotor stage 1 disk. This AD requires visual inspection and fluorescent penetrant inspection (FPI) of the HPT thermal shield and, if cracking is detected, removal from service of the HPT thermal shield, HPT rotor stage 1 disk and HPT rotor stage 2 disk. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 27, 2021.

ADDRESSES: For service information identified in this final rule, contact General Electric Company, 1 Neumann Way, Cincinnati, OH 45215; phone: (513) 552–3272; email: *aviation.fleetsupport@ae.ge.com;* website: *www.ge.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1179.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1179; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Kevin M. Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *Kevin.M.Clark@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all General Electric Company (GE) CF6–80A, CF6–80A1, CF6–80A2, CF6–80A3, CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, CF6–80C2A8, CF6–80C2B1, CF6–80C2B1F, CF6–80C2B1F1, CF6–80C2B1F2, CF6–80C2B2, CF6–80C2B2F, CF6–80C2B3F, CF6–80C2B4, CF6–80C2B4F, CF6–80C2B5F, CF6–80C2B6, CF6–80C2B6F, CF6–80C2B6FA, CF6–80C2B7F, CF6–80C2B8F, CF6–80C2D1F, CF6–80C2K1F, and CF6–80C2L1F model turbofan engines. The NPRM published in the **Federal Register** on February 22, 2021 (86 FR 10496). The NPRM was prompted by an inspection by the manufacturer that revealed cracking of the HPT rotor stage 1 disk caused by increased stress on the HPT rotor stage 1 disk as a result of flange-to-flange cracking on the HPT thermal shield. In the NPRM, the FAA proposed to require visual inspection and FPI of the HPT thermal shield and, if cracking is detected, removal from service of the HPT thermal shield, HPT rotor stage 1 disk and HPT rotor stage 2 disk. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from five commenters. The commenters were Atlas Air, Boeing Commercial Airplanes (Boeing), Delta Air Lines (Delta), United Airlines (United) and the Air Line Pilots Association, International (ALPA). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Update Shop Manual

Atlas Air requested that the FAA revise GE CF6–80C2, ESM 72–53–05, High Pressure Turbine (HPT) Rotor Thermal Shield—Inspection to add the proposed requirement to remove from service the HPT thermal shield, the HPT rotor stage 1 disk, and the HPT rotor stage 2 disk from service if a crack is found, since the thermal shield can be sent to different vendors outside the engine shop. Delta also suggested that the technical data within the Engine Shop Manual (ESM) should be updated to ensure inspection requirements are equivalent across all tasks within the ESM.

The FAA disagrees. Requiring updates to the ESM is unnecessary to correct the unsafe condition identified in this AD. The visual and FPI inspections in the required actions of this AD are the necessary actions to correct the unsafe condition. Operators, at their discretion, may work with the original equipment manufacturer to suggest changes to the ESM to include the inspections required by this AD.

Request To Revise References to Engine Manual

Boeing requested that the FAA update reference to the service information in the Related Service Information section of the NPRM by referencing Revision 90 of the GE CF6–80A Engine Manual and Revision 91 of the CF6–80C2 Engine Manual. These revisions of the respective engines manuals include updated procedures regarding HPT rotor Stage 1 and Stage 2 disk serviceability for these model engines with respect to HPT thermal shield inspection findings.

The FAA agrees and has updated the Related Service Information section of this AD as suggested by the commenter.

Request To Clarify Inspection Instructions

Delta requested that the FAA clarify that the mandated visual and FPI inspections should be accomplished in accordance with the engine manual for the affected engine models.

The FAA disagrees. Operators may use any approved method to perform the visual and FPI inspections required by this AD.

Request To Clarify Engine Applicability

United requested that the FAA remove CF6–80C2B8F model turbofan engines from the applicability of this AD. United commented that two HPT thermal shield configurations exist, part number (P/N) 2787M85P01 and P/N 9315M41P20. Neither of these configurations are applicable to the R88DT HPT rotor installed on CF6–80C2B8F model turbofan engines. United requested that if the FAA considers the CF6–80C2B8F turbofan engine model affected by this AD, then the applicable engine manual should be updated to reflect the inspections required by this AD.

The FAA agrees. This AD is not applicable to the R88DT HPT rotor installed on CF6–80C2B8F model turbofan engines because that rotor configuration does not have an affected thermal shield. The FAA added the applicable part numbers for HPT thermal shields installed on CF6–80A and CF6–80C2 model turbofan engines to the applicability paragraph of this AD.

Support for the NPRM

ALPA supported the NPRM without change.

Conclusion

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

Related Service Information

The FAA reviewed ESM 72–53–00 High Pressure Turbine Rotor Assembly—Disassembly (CF6–80A ESM 72–53–00), dated February 15, 2020 from the GE CF6–80A Engine Manual GEK72501—Rev 90, dated February 15, 2021. CF6–80A ESM 72–53–00 describes procedures for the removal of the HPT thermal shield, the HPT rotor stage 1 disk, and the HPT rotor stage 2 disk installed on CF6–80A model turbofan engines.

The FAA also reviewed ESM 72–53–00 High Pressure Turbine Rotor Assembly—Disassembly (CF6–80C2 ESM 72–53–00), dated December 1, 2019 from the GE CF6–80C2 Engine Manual GEK92451—Rev 91, dated December 1, 2020. CF6–80C2 ESM 72–53–00 describes procedures for the removal of the HPT thermal shield, the HPT rotor stage 1 disk, and the HPT rotor stage 2 disk installed on CF6–80C2 model turbofan engines.

Costs of Compliance

The FAA estimates that this AD affects 1,084 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Perform FPI and visual inspection of HPT thermal shield.	2 work-hours × $85 per hour = $170	$0	$170	$184,280

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace HPT thermal shield	2 work-hours × $85 per hour = $170	$209,600	$209,770
Replace HPT rotor stage 1 disk	2 work-hours × $85 per hour = $170	799,700	799,870
Replace HPT rotor stage 2 disk	2 work-hours × $85 per hour = $170	364,600	364,770

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–14–11 General Electric Company: Amendment 39–21638; Docket No. FAA–2020–1179; Project Identifier AD–2020–00818–E.

(a) Effective Date

This airworthiness directive (AD) is effective August 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) CF6–80A, CF6–80A1, CF6–80A2, CF6–80A3, CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, CF6–80C2A8, CF6–80C2B1, CF6–80C2B1F, CF6–80C2B1F1, CF6–80C2B1F2, CF6–80C2B2, CF6–80C2B2F, CF6–80C2B3F, CF6–80C2B4, CF6–80C2B4F, CF6–80C2B5F, CF6–80C2B6, CF6–80C2B6F, CF6–80C2B6FA, CF6–80C2B7F, CF6–80C2B8F, CF6–80C2D1F, CF6–80C2K1F, and CF6–80C2L1F model turbofan engines with an installed thermal shield having one of the following part numbers: 2787M85P01, 9315M41P09, 9315M41P13, 9315M41P14, 9315M41P15, 9315M41P16, 9315M41P20, 9348M13P01, 9367M63P01, 9367M63P02, 9367M63P03, 9367M63P04, 9367M63P05, 9367M63P06, 9367M63P07, or 9315M41P20.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by an inspection by the manufacturer that revealed cracking of the high-pressure turbine (HPT) rotor stage 1 disk, caused by initial flange-to-flange cracking on the HPT thermal shield between the HPT rotor stage 1 disk and the HPT rotor stage 2 disk. The FAA is issuing this AD to prevent failure of the HPT rotor stage 1 disk and the HPT rotor stage 2 disk. The unsafe condition, if not addressed, could result in uncontained release of the HPT rotor stage 1 and stage 2 disks, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) After the effective date of this AD, at every piece-part exposure of the HPT rotor stage 1 disk, HPT rotor stage 2 disk, or the HPT thermal shield, perform a visual inspection and a fluorescent penetrant inspection of the HPT thermal shield.

(2) During any inspection required by paragraph (g)(1) of this AD, if a crack extending through either the forward or aft flange of the HPT thermal shield is detected, remove the HPT thermal shield, the HPT rotor stage 1 disk, and the HPT rotor stage 2 disk from service.

(h) Installation Prohibition

Do not install onto any engine an HPT rotor stage 1 disk or HPT rotor stage 2 disk that was removed from service due to the requirements of paragraph (g)(2) of this AD.

(i) Definition

For the purpose of this AD, ''piece-part exposure'' is when the HPT rotor stage 1 disk, HPT rotor stage 2 disk, or HPT thermal shield is separated from their mating rotor parts within the HPT rotor module.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

For more information about this AD, contact Kevin M. Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *Kevin.M.Clark@faa.gov.*

(l) Material Incorporated by Reference

None.

Issued on June 25, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15694 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0375; Project Identifier MCAI–2020–01245–R; Amendment 39–21656 AD 2021–15–09]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Leonardo S.p.a. Model AB139 and AW139 helicopters. This AD was prompted by two events of uncommanded emergency flotation system (EFS) deployment during flight. This AD requires replacing certain part-numbered EFS control panels and prohibits installing them. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 27, 2021.

ADDRESSES: For service information identified in this final rule, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.* You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by

searching for and locating Docket No. FAA–2021–0375; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Ronnea Derby, Aerospace Engineer, Denver ACO Branch, Compliance & Airworthiness Division, FAA, 26805 E 68th Ave., Mail Stop: Room 214; Denver, CO 80249; telephone (303) 342–1093; email *Ronnea.L.Derby@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Leonardo S.p.a. Model AB139 and AW139 helicopters with an EFS control panel part number (P/N) 3G9560V00556 (for use with night vision goggle) or 3G9560V00557 (standard) installed. The NPRM published in the **Federal Register** on May 25, 2021 (86 FR 28040). In the NPRM, the FAA proposed to require replacing EFS control panel P/Ns 3G9560V00556 and 3G9560V00557 with EFS control panel P/Ns 3G9560V00559 and 3G9560V00558, respectively. The NPRM also proposed to prohibit installing EFS control panel P/Ns 3G9560V00556 and 3G9560V00557 on any helicopter. The NPRM was prompted by EASA AD 2015–0172, dated August 21, 2015 (EASA AD 2015–0172), issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for AgustaWestland S.p.A (formerly Agusta S.p.A.), AgustaWestland Philadelphia Corporation (formerly Agusta Aerospace Corporation) (now Leonardo S.p.a.) Model AB139 and AW139 helicopters with an EFS installed. EASA advises of two events of uncommanded EFS deployment during flight. Subsequent investigation revealed that these conditions had been caused by improper design of EFS control panel P/Ns 3G9560V00556 (for use with night vision goggle) and 3G9560V00557 (standard). This condition, if not addressed, could result in reduced control of the helicopter.

Accordingly, EASA AD 2015–0172 requires replacing EFS control panel P/Ns 3G9560V00556 and 3G9560V00557 with EFS control panel P/Ns 3G9560V00559 and 3G9560V00558, respectively. EASA AD 2015–0172 also prohibits installing EFS control panel P/Ns 3G9560V00556 and 3G9560V00557 on any helicopter.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA reviewed the relevant data and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these helicopters.

Related Service Information

The FAA reviewed AgustaWestland Bollettino Tecnico No. 139–374, dated July 6, 2015. This service information specifies procedures for replacing EFS control panel P/Ns 3G9560V00556 and 3G9560V00557 with EFS control panel P/Ns 3G9560V00559 and 3G9560V00558, respectively. This service information also notes that EFS control panel P/Ns 3G9560V00556 and 3G9560V00557 can be upgraded by following Sirio Panel Service Bulletins 6WS–MI100135 Ed.01 and 6WS–MI100134 Ed.01.

Differences Between This AD and the EASA AD

EASA AD 2015–0172 applies to Model AB139 and AW139 helicopters with an EFS installed, whereas this AD applies to those model helicopters with EFS control panel P/N 3G9560V00556 (for use with night vision goggle) or 3G9560V00557 (standard) installed instead. EASA AD 2015–0172 specifies replacing an affected EFS control panel within a compliance time of flight hours or months, whichever occurs first, based on helicopter configuration, whereas this AD requires that replacement within a shorter compliance time in hours time-in-service but the same number of months, based on helicopter configuration instead.

Costs of Compliance

The FAA estimates that this AD affects 133 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Replacing an EFS control panel takes about 1 work-hour and parts cost about $12,342 for an estimated cost of $12,427 per helicopter and up to $1,652,791 for the U.S. fleet.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2021–15–09 Leonardo S.p.a.: Amendment 39–21656; Docket No. FAA–2021–0375; Project Identifier MCAI–2020–01245–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 27, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AB139 and AW139 helicopters, certificated in any category, with an emergency flotation system (EFS) control panel part number (P/N) 3G9560V00556 (for use with night vision goggle) or 3G9560V00557 (standard) installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 3212, Emergency Flotation Section.

(e) Unsafe Condition

This AD was prompted by two events of uncommanded EFS deployment during flight. The FAA is issuing this AD to address improper design of certain EFS control panels. The unsafe condition, if not addressed, could result in reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) At the following compliance time, replace EFS control panel P/N 3G9560V00556 or 3G9560V00557 with EFS control panel P/N 3G9560V00559 or 3G9560V00558, respectively:

(i) For helicopters with EFS P/N 3G9560F00111 or 3G9560F00113, with Aerosekur floats with ''pyrotechnical'' inflation system P/N 3G9560V01051 installed, within 94 hours time-in-service (TIS) or 3 months after the effective date of this AD, whichever occurs first.

(ii) For helicopters with EFS P/N 3G9560F00111 or 3G9560F00113, with Aerosekur floats with ''SMA'' inflation system P/N 3G9560V01052 installed, within 377 hours TIS or 12 months after the effective date of this AD, whichever occurs first.

(iii) For helicopters with EFS P/N 3G9560F00212 with Aerosekur floats with ''fuse disk'' inflation system P/N 3G9560V02051 installed, within 565 hours TIS or 18 months after the effective date of this AD, whichever occurs first.

(2) As of the effective date of this AD, do not install EFS control panel P/N 3G9560V00556 or 3G9560V00557 on any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

(1) For more information about this AD, contact Ronnea Derby, Aerospace Engineer, Denver ACO Branch, Compliance & Airworthiness Division, FAA, 26805 E 68th Ave., Mail Stop: Room 214; Denver, CO 80249; telephone (303) 342–1093; email *Ronnea.L.Derby@faa.gov.*

(2) The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2015–0172, dated August 21, 2015. You may view the EASA AD at *https://www.regulations.gov* in Docket No. FAA–2021–0375.

Issued on July 15, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15481 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0003; Airspace Docket No. 21–ACE–5]

RIN 2120–AA66

Amendment of Class D and E Airspace and Revocation of Class E Airspace; Cape Girardeau, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class D and Class E airspace and revokes Class E airspace at Cape Girardeau Regional Airport, Cape Girardeau, MO. The FAA is making this action as the result of an airspace review caused by the decommissioning of the Marion very high frequency (VHF) omnidirectional range (VOR) navigation aid as part of the VOR Minimum Operational Network (MON) Program. The name of the localizer is also updated to coincide with the FAA's aeronautical database. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Effective 0901 UTC, October 7, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class D airspace; amends the Class E surface airspace; amends the Class E airspace extending upward from 700 feet above the surface; and revokes the Class E airspace area designated as an extension to Class D and Class E surface

airspace at Cape Girardeau Regional Airport, Cape Girardeau, MO, to support IFR operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 22368, April 28, 2021) for Docket No. FAA–2021–0003 to amend Class D airspace, Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface at Cape Girardeau Regional Airport, Cape Girardeau, MO, to accommodate area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this airport. Also, the FAA is removing the Class E airspace area designated as an extension to Class D and Class E surface areas at Cape Girardeau Regional Airport, as it is no longer required.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and Class E airspace designations are published in Paragraphs 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by: Amending the Class D airspace at Cape Girardeau Regional Airport, Cape Girardeau, MO, by adding an extension 1 mile each side of the 021° bearing from the airport extending from the 4.1-mile radius to 4.4 miles north of the airport; and adding an extension 1 mile each side of the 106° bearing from the Cape Girardeau RGNL: RWY 10–LOC extending from the 4.1-mile radius of the airport to 4.4 miles east of the Cape Girardeau RGNL: RWY 10–LOC;

Amending the Class E surface airspace at Cape Girardeau Regional Airport by removing the vertical limit on the airspace as it is not required; adding an extension 1 mile each side of the 021° bearing from the airport extending from the 4.1-mile radius to 4.4 miles north of the airport; and adding an extension 1 mile each side of the 106° bearing from the Cape Girardeau RGNL: RWY 10–LOC extending from the 4.1-mile radius of the airport to 4.4 miles east of the Cape Girardeau RGNL: RWY 10–LOC;

Removing the Class E airspace area designated as an extension to Class D and Class E surface area at Cape Girardeau Regional Airport as it is no longer required;

And amending the Class E airspace extending upward from 700 feet above the surface at Cape Girardeau Regional Airport by removing the Cape Girardeau VOR/DME and associated extension from the airspace legal description; updating the bearing of the north extension to 021° (previously 023°); updating the bearing of the east extension to 106° (previously 108°) and changing the reference of the extension to the Cape Girardeau RGNL: RWY 10–LOC (previously the airport); updating the bearing of the south extension to 201° (previously 203°); and updating the bearing of the west extension to 286° (previously 280°); and updating the name of the Cape Girardeau RGNL: RWY 10–LOC (previously Cape Girard Regional Localizer) to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Marion VOR, which provided navigation information for the instrument procedures this airport, as part of the VOR MON Program.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ACE MO D Cape Girardeau, MO [Amended]

Cape Girardeau Regional Airport, MO
(Lat. 37°13′31″N, long. 89°34′15″W)
Cape Girardeau RGNL: RWY 10–LOC
(Lat. 37°13′18″N, long. 89°33′25″W)

That airspace extending upward from the surface to and including 2,800 feet within a 4.1-mile radius of Cape Girardeau Regional Airport, and within 1 mile each side of the 021° bearing from the airport extending from the 4.1-mile radius of the airport to 4.4 miles north of the airport, and within 1 mile each side of the 106° bearing from the Cape Girardeau RGNL: RWY 10–LOC extending from the 4.1-mile radius of the airport to 4.4 miles east of the Cape Girardeau RGNL: RWY 10–LOC. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Surface Airspace.

* * * * *

ACE MO E2 Cape Girardeau, MO [Amended]

Cape Girardeau Regional Airport, MO
(Lat. 37°13′31″N, long. 89°34′15″W)
Cape Girardeau RGNL: RWY 10–LOC
(Lat. 37°13′18″N, long. 89°33′25″W)

That airspace extending upward from the surface within a 4.1-mile radius of Cape Girardeau Regional Airport, and within 1 mile each side of the 021° bearing from the airport extending from the 4.1-mile radius of the airport to 4.4 miles north of the airport, and within 1 mile each side of the 106° bearing from the Cape Girardeau RGNL: RWY 10–LOC extending from the 4.1-mile radius of the airport to 4.4 miles east of the Cape Girardeau RGNL: RWY 10–LOC. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to Class E Surface Area.

* * * * *

ACE MO E4 Cape Girardeau, MO [Removed]

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

* * * * *

ACE MO E5 Cape Girardeau, MO [Amended]

Cape Girardeau Regional Airport, MO
(Lat. 37°13′31″N, long. 89°34′15″W)
Cape Girardeau RGNL: RWY 10–LOC
(Lat. 37°13′18″N, long. 89°33′25″W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Cape Girardeau Regional Airport, and within 1.9 miles each side of the 021° bearing from the airport extending from the 6.6-mile radius of the airport to 7.3 miles north of the airport, and within 3.8 miles each side of the 106° bearing from the Cape Girardeau RGNL: RWY 10–LOC extending from the 6.6-mile radius of the airport to 14 miles east of the Cape Girardeau RGNL: RWY 10–LOC, and within 2 miles each side of the 201° bearing from the airport from the 6.6-mile radius of the airport to 7.5 miles south of the airport, and within 2 miles each side of the 286° bearing from the airport extending from the 6.6-mile radius of the airport to 7.4 miles west of the airport.

Issued in College Park, Georgia, on July 19, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–15674 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1208; Airspace Docket No. 20–AAL–46]

RIN 2120–AA66

Establishment of Class E Airspace; Wilder Runway LLC, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface of the earth at Wilder Runway LLC Airport, Port Alsworth, AK. This action will accommodate new area navigation (RNAV) procedures and ensure the safety and management of instrument flight rule (IFR) operations within the National Airspace System. This action will also correct an error in the airport name to match the FAA's database.

DATES: Effective 0901 UTC, October 7, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov//air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it will establish Class E airspace extending upward from 700 feet above the surface of the earth to support IFR operations at Wilder Runway LLC Airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 10505; February 22, 2021) for Docket No. FAA–2020–1208 to establish Class E airspace at Wilder Runway LLC Airport, Port Alsworth, AK. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA, none were received.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace, extending upward from 700 feet above the surface, at Wilder Runway LLC Airport. The Class E airspace is established within a 2.5 mile radius of the airport beginning at the point the 308° bearing from the airport intersects the 2.5-mile radius clockwise to the point the 79° bearing from the airport intersects the 2.5-mile radius. This area accommodates circling north of runway 6/24. In addition, this area includes that airspace within a 7.3 mile radius of the airport beginning at the point the 230° bearing from the airport intersects the 7.3-mile radius clockwise to the point the 271° bearing

from the airport intersects the 7.3-mile radius. This area protects aircraft using the RNAV approach to runway 6 and departures until reaching 1,200 feet AGL. In addition, the FAA identified that the airport name, contained in the NPRM, was not consistent with the National Airspace System Resource (NASR) database. This action will update the airport name to match NASR.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

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

* * * * *

AAL AK E5 Port Alsworth, AK [NEW]

Wilder Runway LLC Airport, AK
(Lat. 60°11′55″ N, long. 154°19′23″ W)

That airspace extending upward from 700 feet above the surface within 7.3 mile radius of Wilder Runway LLC Airport beginning at the point the 230° bearing from the airport intersects the 7.3-mile radius clockwise along the 7.3-mile radius to the point the 271° bearing intersects the 7.3-mile radius, thence east to the point the 308° bearing from the airport intersects an arc within a 2.5 mile radius of the airport, thence clockwise along the 2.5-mile arc to the point the 79° bearing intersects the 2.5-mile arc thence southwest to the point of beginning.

Issued in Des Moines, Washington, on July 15, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–15492 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0004; Airspace Docket No. 20–AAL–55]

RIN 2120–AA66

Establishment of Class E Airspace; Crooked Creek, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface of the earth at Crooked Creek Airport, Crooked Creek, AK. This action will accommodate new area navigation (RNAV) procedures and ensure the safety and management of instrument flight rule (IFR) operations within the National Airspace System.

DATES: Effective 0901 UTC, October 7, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov//air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the surface of the earth to support IFR operations at Crooked Creek Airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 10882; February 23, 2021) for Docket No. FAA–2021–0004 to establish Class E airspace at Crooked Creek Airport, Crooked Creek, AK. Interested parties were invited to

participate in this rulemaking effort by submitting written comments on the proposal to the FAA, none were received.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace, extending upward from 700 feet above the surface, at Crooked Creek Airport. The Class E airspace is established within a 2 mile radius of the airport, excluding that area within the Stony B Military Operations Area, and that airspace within 2 miles each side of the 332° bearing extending from the 2-mile radius to 8.5 miles northwest of the airport. This airspace protects aircraft using the RNAV approach to runway 14 and departures until reaching 1,200 feet AGL.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

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

* * * * *

AAL AK E5 Crooked Creek, AK (NEW)

Crooked Creek Airport, AK
(Lat. 61°52′4″ N, long. 158°8′6″ W)

That airspace extending upward from 700 feet above the surface within a 2-mile radius of Crooked Creek Airport, and that airspace within 2 miles each side of the 332° bearing extending from the 2-mile radius to 8.5 miles northwest of the airport excluding that airspace within the Stony B MOA.

Issued in Des Moines, Washington, on July 15, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–15491 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA–2021–0010]

RIN 0960–AI64

Flexibility in Evaluating ''Close Proximity of Time'' Due to COVID–19 Related Barriers to Healthcare

AGENCY: Social Security Administration.

ACTION: Temporary final rule with request for comments.

SUMMARY: Since the outset of the COVID–19 national public health emergency, many individuals have experienced barriers that prevent them from timely accessing healthcare. In response to those barriers, we are issuing this rule to temporarily revise our requirement in the Listing of Impairments (listings) that, for purposes of applying several of our musculoskeletal disorder listings, all relevant medical criteria be present simultaneously or ''within a close proximity of time,'' which we define as being ''within a consecutive 4-month period.'' While this rule is in effect, we will find that the evidence of a musculoskeletal disorder is present ''within a close proximity of time'' if the available evidence establishes such a condition within a consecutive 12-month period. We expect that this temporary change to our rules will allow us to make findings of disability in appropriate cases in which individuals have experienced barriers to access to healthcare because of the COVID–19 national public health emergency.

DATES:

Effective date: This temporary final rule is effective on July 23, 2021. For more information, *see* **SUPPLEMENTARY INFORMATION**.

Comment date: We invite written comments. Comments must be submitted on or before September 21, 2021.

Expiration date: Unless we extend the expiration date by a final rule published in the **Federal Register**, this temporary final rule will cease to be effective 6 months after the effective date of a determination by the Secretary of Health and Human Services under section 319 of the Public Health Service Act, 42 U.S.C. 247d, that the COVID–19 national public health emergency no longer exists. We will publish a document in the **Federal Register** announcing the expiration date. For more information, *see* **SUPPLEMENTARY INFORMATION**.

ADDRESSES: You may submit comments by any one of three methods—internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket No. SSA–2021–0010 so that we may associate your comments with the correct rule.

Caution: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. *Internet:* We strongly recommend that you submit your comments via the internet. Please visit the Federal eRulemaking portal at *http://www.regulations.gov.* Use the search function to find docket number SSA–2021–0010. The system will issue a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comments to be viewable.

2. *Fax:* Fax comments to (410) 966–2830.

3. *Mail:* Mail your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 3100 West High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401.

Comments are available for public viewing on the Federal eRulemaking portal at *http://www.regulations.gov* or in person, during regular business hours, by arranging with the contact person identified in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Edward Sosar, Office of Regulations and Reports Clearance, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 966–2341. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services issued a determination under section 319 of the Public Health Service Act on January 31, 2020 that a national public health emergency exists as of January 27, 2020 because of the COVID–19 pandemic.[1] The Secretary has renewed his determination several times since then, most recently on July 19, 2021 (effective July 20, 2021).[2] We are issuing this temporary final rule to address the ongoing effects of the COVID–19 national public health emergency. The effective date of this temporary final rule will help us ensure that we provide affected claimants with the benefit of the flexibilities offered by this rule. On April 1, 2021, we instructed our adjudicators to temporarily hold claims in which all elements of musculoskeletal disorders listings 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, 1.23, 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, or 101.23 were present within a consecutive 12-month period, but not within a consecutive 4-month period, and it was not possible to process a fully favorable determination or decision in some other way. By holding claims that would benefit from the flexibilities in this rule, we will process claims affected by this rule on or after the effective date of this rule. As we explain in more detail below, we will continue to apply this rule until 6 months after effective date of a determination by the Secretary of Health and Human Services under section 319 of the Public Health Service Act that the national public health emergency related to the COVID–19 pandemic no longer exists.

Background

On December 3, 2020, we published the final rule, Revised Medical Criteria for Evaluating Musculoskeletal Disorders, which became effective on April 2, 2021, revising the criteria in the listings that we use to evaluate disability claims involving musculoskeletal disorders in adults and children at the third step of our sequential evaluation process under titles II and XVI of the Social Security Act (Act).[3] The final rule, among other things, revised the listings in response to the decision in *Radford* v. *Colvin,* 734 F.3d 288 (4th Cir. 2013). The final rule required that, for the purposes of applying certain listings,[4] all of the required medical criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing.[5] We defined the phrase ''within a close proximity of time'' to mean ''that *all* of the relevant criteria must appear in the medical record within a consecutive 4-month period'' (emphasis in original).[6] We also provided that ''[w]hen the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset.'' [7]

We established the consecutive 4-month period as a criterion to meet the level of severity in the listings based on our extensive research of relevant medical literature and clinical guidelines. In our notice of proposed rulemaking, we also specifically asked interested members of the public to comment on this issue and provide us with any studies and data that supported their comments; [8] however, no studies or data were submitted. In the final rule, we concluded that the consecutive 4-month period is consistent with instructions providers receive for scheduling patients,[9] the general standard of care,[10] and the frequency of healthcare visits by individuals with musculoskeletal conditions.[11] At the same time, the consecutive 4-month period in the rules provides some leeway for the claimant, because the standard for patient revisits is once every 3 months.[12] Our rules recognize that one visit alone may not ensure all necessary criteria required for a medical listing will be appropriately documented; however, the consecutive 4-month time period provides a sufficient period to ensure the criteria are present within a close proximity of time and that the claimant's

[1] (*https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*).

[2] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-19July2021.aspx.*

[3] 85 FR 78164 (2020).

[4] Listings 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, 1.23, 101.15, 101.16, 101.17, 101.18, 101.20D, 101.22, and 101.23.

[5] See 20 CFR appendix 1 to subpart P of part 404 1.00C7b and 101.00C7b.

[6] Id.

[7] Id.

[8] 83 FR 20646, 20647 (May 7, 2018).

[9] 85 FR at 78169 n.37 (citing Bavafa, H., Savin, S., & Terwiesch, C. (2019). Redesigning Primary Care Delivery: Customized Office Revisit Intervals and E-Visits. *https://dx.doi.org/10.2139/ssrn.2363685.* Paper referenced by Bavafa: Schectman, G., G. Barnas, P. Laud, L. Cantwell, M. Horton, E.J. Zarling. 2005. Prolonging the return visit interval in primary care. *The American Journal of Medicine, 118*(4) 393–399.)

[10] 85 FR at 78169 n.34 (citing Gore, M., Sadosky, A., Stacey, B.R., Tai, K.S., & Leslie, D. (2012). The burden of chronic low back pain: Clinical comorbidities, treatment patterns, and health care costs in usual care settings. *Spine, 37*(11), E668–E677. *https://doi.org/10.1097/BRS.0b013e318241e5de.*)

[11] 85 FR at 78169 n.35 (citing BMUS: The Burden of Musculoskeletal Diseases in the United States. In: BMUS: The Burden of Musculoskeletal Diseases in the United States [internet]. [cited 15 July 2020]. *https://www.boneandjointburden.org/fourth-edition/viiic2/utilization-condition-group.)*

[12] See 85 FR at 78169 n.36 (citing *J Gen Intern Med.* 1999 Apr; 14(4): 230–235. doi: *10.1046/j.1525–1497.1999.00322.x Lisa M Schwartz,* MD, MS, *Steven Woloshin,* MD, MS, *John H Wasson,* MD, *Roger A Renfrew,* MD, and *H Gilbert Welch,* MD, MPH, Dartmouth Primary Care Cooperative Research Network.)

musculoskeletal disorder meets the requisite severity for the listing.

Our use of the consecutive 4-month proximity of time requirement is also consistent with the standard recognized by the Veterans Health Administration (VHA) and Department of Defense (DoD), as set out in their clinical practice guidelines.[13] For example, the VHA and DoD's Clinical Practice Guideline for the Management of Medically Unexplained Symptoms: Chronic Pain and Fatigue directs initial revisits at 2 to 3 week intervals, with visits every 3 to 4 months once the patient is doing well.[14] Similarly, the VHA's and DoD's Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain describes the duration of time for intervention, based on a systematic review, as requiring a minimum follow-up for effectiveness of 12 weeks and recommends monthly reassessment after initiation of therapy if low back pain continues and no serious specific underlying cause of low back pain is found.[15]

Rationale for This Rule

As noted above, on January 31, 2020, the Secretary of Health and Human Services declared COVID–19 a national public health emergency. The COVID–19 national public health emergency has dramatically changed the provision of, and access to, healthcare services throughout the country. Individuals with musculoskeletal impairments who, before the national public health emergency, would seek and receive healthcare at a frequency consistent with the standards cited above, now might be unable or choose not to seek care in the same manner and frequency. This is due in part to healthcare organizations and government agencies such as the Centers for Medicare & Medicaid Services (CMS)[16] prioritizing the most urgent services and encouraging patients to delay other procedures during the pandemic. For example, the North American Spine Society (NASS) provided guidance for delaying non-emergent procedures for people with chronic spinal conditions.[17]

Likewise, many individuals have delayed or deferred important treatment due to closures of medical offices, fears of contracting COVID–19 infection (including having a high risk individual in the household), and other challenges created or exacerbated by the pandemic, such as difficulty accessing transportation. According to one source, among the general U.S. population reporting delayed care for serious problems during the pandemic, 69% cited nonfinancial access barriers, such as being unable to get an appointment, find a physician who would see them, or access the care location.[18] Additionally, the National Center for Health Statistics estimated that 41% of U.S. adults had delayed or avoided medical care, including urgent or emergency care (12%) and routine care (32%) because of concerns about COVID–19.[19]

We are also temporarily changing the consecutive 4-month close proximity of time rule to a consecutive 12-month rule because the manner of care provided changed throughout the COVID–19 national public health emergency. To be responsive to this change in the manner of care, we instructed our adjudicators to temporarily hold claims that would benefit from the flexibilities in this rule, so we will process claims affected by this rule on or after the effective date of this rule. Due to safety concerns, many healthcare providers shifted to emphasizing or exclusively scheduling telehealth or virtual visits. The optimization of telehealth is consistent with the guidance issued by many specialist organizations, such as NASS,[20] the American College of Surgeons (ACS),[21] the American Academy of Orthopedic Surgeons (AAOS),[22] and the American College of Rheumatology (ACR).[23]

Although many individuals access telehealth visits successfully, the clinical signs and findings required by some of the listings may not be present in the telehealth record due to the limitations of telemedicine. While testing by the patient is possible through telehealth, there are limits in provocative testing (that is, testing that manipulates the areas where you have pain in order to reproduce the pain), discrete palpation (that is, a technique that uses targeted pressure to identify and quantify the abnormalities of the musculoskeletal system, such as warmth, swelling, pain, tenderness, and trigger points), and strength or stability testing.[24] During the beginning of the COVID–19 pandemic, orthopedists created guidelines for virtual examinations of patients through telemedicine, and found that while the patient could perform many tests, there are inherent limitations to testing in this manner. For example, the authors recommend using another person to hold the camera during gait examination to get a better view of the patient's gait mechanics, which is not always possible.[25] Further, the VHA has found that although patients appreciate telehealth, many are unable to complete exams that require precise measurements, such as range of motion or reflexes.[26]

Consequently, disability claimants with musculoskeletal disorders of the severity required by the listings who would have been able to provide evidence that their musculoskeletal disorder met the consecutive 4-month close proximity of time requirement

[13] 85 FR at 78169 n.38 (citing Veterans Health Administration & Department of Defense. (2001). VHA/DoD Clinical Practice Guideline for the Management of Medically Unexplained Symptoms: Chronic Pain and Fatigue. *https://www.healthquality.va.gov/guidelines/MR/mus/mus_fulltext.pdf.*)

[14] Id.

[15] 85 FR at 78169–70 (citing Veterans Health Administration & Department of Defense. (2017). VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. *https://www.healthquality.va.gov/guidelines/Pain/lbp/VADoDLBPCPG092917.pdf.*)

[16] Centers for Medicare & Medicaid Services (CMS) Recommendations: Re-opening Facilities to Provide Non-emergent Non-COVID–19 Healthcare (*https://www.cms.gov/files/document/covid-recommendations-reopening-facilities-provide-non-emergent-care.pdf); see also Non-Emergent, Elective Medical Services, and Treatment Recommendations (https://www.cms.gov/files/document/cms-non-emergent-elective-medical-recommendations.pdf.*)

[17] *https://www.spine.org/Portals/0/assets/downloads/Publications/NASSInsider/NASSGuidanceDocument040320.pdf.*

[18] Delayed Care with Harmful Health Consequences—Reported Experiences from National Surveys During Coronavirus Disease 2019 | Infectious Diseases | JAMA Health Forum | JAMA Network. *See also* The Impact of Coronavirus on Households Across America (*https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2020/09/NPR-RWJF-Harvard-National-Report_092220_Final1-4.pdf*) and COVID–19: Experiences Among the Medicare Population (*https://www.cms.gov/files/document/medicare-current-beneficiary-survey-covid-19-data-snapshot.pdf.*)

[19] Reduced Access to Care: Household Pulse Survey (National Center for Health Statistics) (*https://www.cdc.gov/nchs/covid19/pulse/reduced-access-to-care.htm.*)

[20] *https://www.spine.org/Portals/0/assets/downloads/Publications/NASSInsider/NASSGuidanceDocument040320.pdf.*

[21] COVID–19 Guidelines for Triage of Orthopaedic Patients (*https://www.facs.org/covid-19/clinical-guidance/elective-case/orthopaedics*).

[22] Navigating the COVID–19 Pandemic (*https://www.aaos.org/globalassets/about/covid-19/aaos-clinical-considerations-during-covid-19.pdf*).

[23] COVID–19 Clinical Guidance for Adult Patients with Rheumatic Diseases (*https://www.rheumatology.org/Portals/0/Files/ACR-COVID-19-Clinical-Guidance-Summary-Patients-with-Rheumatic-Diseases.pdf*).

[24] Tanaka et al. (2020). *Telemedicine in the Era of COVID–19: The Virtual Orthopaedic Examination.* The Journal of Bone and Joint Surgery, Incorporated, 00:e1 (1–7) *http://dx.doi.org/10.2106/JBJS.20.00609.*

[25] Laskowski, et al. (2020). *The Telemedicine Musculoskeletal Examination.* Mayo Clinic Proc. 95(8) *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7395661/.*

[26] Baus, Shanna, PA–C. *Telehealth & Disability Items: Veterans Health Administration.* Presentation to the Standing Committee of the National Academies of Science and Medicine Health and Medicine Division, on December 1, 2020.

before the COVID–19 national public health emergency may now have more difficulty producing evidence to meet the standard. It is possible that, in light of the pandemic and the temporary changes in healthcare described above, claimants have scheduled fewer clinical visits or have been afforded fewer appointments that would allow them to provide the necessary evidence. Because such a claimant would lack the necessary documentation to meet the listing in the absence of this temporary change, we would not find the claimant disabled under the listings, although we could make a finding of disability at later steps of our sequential evaluation process in appropriate cases.

In recognition of the economic and social services crisis caused by the COVID–19 national public health emergency, the President published Executive Order 14002 *Economic Relief Related to the COVID–19 Pandemic,*[27] which directed Federal agencies to consider actions to improve access to and reduce unnecessary barriers to Federally-funded programs. We are issuing this rule in furtherance of the goals in the Executive Order.

This rule will remain in effect until 6 months after the effective date of a determination by the Secretary of Health and Human Services under section 319 of the Public Health Service Act, 42 U.S.C. 247d, that the national public health emergency resulting from the COVID–19 pandemic no longer exists, which will afford claimants the opportunity to attend scheduled appointments that may have been delayed during the national public health emergency, allow us time to adjudicate claims affected by the rule, and allow sufficient time to notify the adjudicative community of the change. We will continue to apply the consecutive 12-month period until 6 months after the Secretary of HHS determines that the COVID–19 national public health emergency no longer exists to allow time for health care access to normalize back to pre-pandemic period levels and to account for potential backlogs in medical care that may continue to interfere with access to the relevant care and documentation needed to satisfy the listing criteria. Additionally, the expiration date included in this temporary final rule will provide us with the time necessary to publish a document in the **Federal Register** to advise the public of the date on which this rule will no longer be effective, communicate the change to adjudicators and the public, update our materials that reference the consecutive 12-month period, and process claims where the medical care was received prior to the end of the COVID–19 national public health emergency.

[27] 86 FR 7229 (2021).

Summary of the Changes

This rule adds a new section 1.00C7a and 101.00C7a to the musculoskeletal disorders listings. The rule also redesignates current sections 1.00C7a and 1.00C7b as 1.00C7b and 1.00C7c, respectively, and 101.00C7a and 101.00C7b as 101.00C7b and 101.00C7c, respectively. New sections 1.00C7a and 101.00C7a define the term ''pandemic period'' to mean ''the period beginning on April 2, 2021 and ending on the date that is 6 months after the effective date of a determination by the Secretary of Health and Human Services under section 319 of the Public Health Service Act, 42 U.S.C. 247d, that the national public health emergency resulting from the COVID–19 pandemic no longer exists.'' Redesignated and revised sections 1.00C7c and 101.00C7c provide that, for purposes of listings 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, 1.23, 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, the phrase ''within a close proximity of time'' means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the pandemic period. For claims that we determine or decide during the pandemic period, we provide that all of the relevant criteria must appear in the medical record within a consecutive 12-month period.

Regulatory Procedures

Justification for Issuing a Rule Without Notice and Comment

We follow the Administrative Procedure Act's (APA) rulemaking procedures specified in 5 U.S.C. 553 when we develop regulations. Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final rule. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(B)).

We find that there is good cause under 5 U.S.C. 553(b)(B) to issue this rule without prior public comment because prior public comment is impracticable and contrary to public interest.

We find that public comment is impracticable because the delay associated with the public comment process would impede our ability to provide this flexibility to claimants affected by the changed nature of healthcare. The delay associated with the public comment process would also affect our ability to operate efficiently and provide appropriate public service because it would require us to hold or readjudicate cases affected by this change, possibly delaying benefits to disabled individuals. People eligible for disability benefits are, by definition, not able to engage in substantial gainful activity.[28] Therefore, many applicants may experience immediate and severe financial hardship,[29] placing them at risk of losing their homes, means of transportation, access to health care, and other important resources, in addition to experiencing increased stress as they await the outcome of their case and their award of benefits. This is particularly true for the population that is eligible for Supplemental Security Income (SSI) benefits, which has, by definition, severely limited income and financial resources.[30] An unnecessary delay during this vulnerable period, particularly in the context of the economic and other hardships caused by the pandemic, would cause significant harm and detract substantially from the effectiveness of the disability program in providing meaningful economic relief for disabled

[28] 42 U.S.C. 223(d)(1) and 1614(a)(3)(A), 20 CFR 404.1505, 404.1572, 416.905, 416.972.

[29] See Bailey, Michelle Stegman and Jeffrey Hemmeter. *Characteristics of Noninstitutionalized DI and SSI Program Participants, 2013 Update,* Research and Statistics Note No. 2015–02. Washington, DC: Office of Research, Evaluation, and Statistics, Office of Retirement and Disability Policy, Social Security Administration, September 2015, *https://www.ssa.gov/policy/docs/rsnotes/rsn2015-02.html,* which shows that 51 percent of DI beneficiaries and 63 percent of SSI beneficiaries have household incomes below the poverty level, excluding their DI and SSI payments. The study also found that DI payments represented an 85 percent reduction in the poverty gap and SSI payments represented a 68 percent reduction in the poverty gap for beneficiaries. See also [SSA] Social Security Administration, *National Beneficiary Survey: Disability Statistics, 2015,* SSA Publication No. 13–11826. Washington, DC: SSA. *https://www.ssa.gov/policy/docs/statcomps/nbs/2015/nbs-statistics-2015.pdf,* which shows that over 45 percent of disability beneficiaries have a household income lower than the poverty level. Additionally, *see Mathews* v. *Eldridge,* 424 U.S. 319, 342 (1976) (''in view of . . . the typically modest resources of the family unit of the physically disabled worker, the hardship imposed upon the erroneously terminated disability recipient may be significant.''); *White* v. *Mathews,* 559 F.2d 852 (2d Cir. 1977) (''The disability insurance program is designed to alleviate the immediate and often severe hardships that result from a wage-earner's disability. In that context, delays . . . detract seriously from the effectiveness of the program.'').

[30] 42 U.S.C. 1611(a), 20 CFR 416.202.

individuals. [31] Even if they receive the same benefits at a later date, these individuals may suffer from long term or permanent consequences of the lost income during the period of delay.

We also find that delaying immediate implementation of this temporary final rule to obtain public comment would be contrary to the public interest because it would prolong the time it would take to adjudicate claims and provide benefits to claimants. This rule is intended to provide us with flexibility to determine that an individual's musculoskeletal disorder meets the requirements of the listings, considering the emerging evidence regarding changes in healthcare delivery that have resulted from the COVID–19 national public health emergency. It also provides for claimants to receive needed benefits at a time when they are financially and medically vulnerable due to onset of disability and the COVID–19 pandemic, based on the evidence that is likely to be in their file during the pandemic. Providing the opportunity for public comment before we implement this rule would prevent us from acting within a meaningful timeframe to account for current access-to-care limitations that prevent claimants who may meet the listing from establishing requisite evidence to show it, because the pandemic-related barriers to access of care that this rule attempts to alleviate would continue to occur. Providing opportunity for prior public comment could also result in the rule taking effect only after the proposed expiration date, when access to care has returned to pre-pandemic norms, which would negate the need for the rule. Consequently, if we offered the opportunity for public comment prior to immediate temporary implementation, we would be unable to offer relief to affected claimants in a timely manner, and we would be required to delay our adjudications of certain disability claims impacted by this temporary final rule and be unable to pay needed benefits to affected individuals in a timely manner. The delay associated with a public comment period would also be contrary to the public interest because it would reduce the effectiveness of the rule and the more flexible timeframe we are establishing. Prior public comment would therefore defeat the purpose of this rule, which is to provide effective and timely relief and ensure economic security to individuals affected by the changed nature of healthcare delivery.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the date of this rule provided for in 5 U.S.C. 553(d)(3). So, we are making this temporary final rule effective upon publication.

We are making this temporary final rule effective on the date of publication. However, we invite public comment on all aspects of the temporary final rule as they may apply after the effective date, including: The definition of the ''pandemic period'' during which we will apply expanded flexibility in the ''close proximity of time'' standard; the appropriate standard for ''close proximity of time'' to account for barriers to access to care; information about barriers to access to care and disproportionate burdens faced by any subset of the population; and the expiration date of this rule. Please share any supporting information that you might have. We will consider any substantive comments we receive within 60 days of the publication of this temporary final rule and will issue a revised final rule if necessary after we consider the public comments. We will also study the application of this temporary final rule in our program.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this temporary final rule meets the criteria for a significant regulatory action under Executive Order 12866 and is subject to OMB review.

Executive Order 13132 (Federalism)

We analyzed this rule under the principles and criteria established by Executive Order 13132 and determined that the rule will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that this rule will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Regulatory Flexibility Act

We certify that this rule will not have a significant economic impact on a substantial number of small entities, because it affects only individuals. Therefore, a Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Anticipated Costs to Our Programs: Our Office of the Chief Actuary (OCACT) was not able to provide a specific cost estimate for this temporary final rule, as it does not have any reliable information on which to base program cost estimates. Additionally, this temporary final rule is to be in effect until 6 months after the Secretary of Health and Human Services determines the COVID–19 national public health emergency no longer exists, and it is unknown how long it will be until such declaration is made.

Anticipated Administrative Costs to SSA: Our Office of Budget, Finance, and Management notes the unknown magnitude on allowance rates and ambiguity in the effective time period for this temporary final rule, but expects this change will have a minimal administrative effect on the agency.

Paperwork Reduction Act

This rule does not create any new or affect any existing collections and, therefore, does not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure; Blind, Disability benefits; Old-age, survivors, and disability insurance; Reporting and recordkeeping requirements; Social Security.

20 CFR Part 416

Administrative practice and procedure; Aged, Blind, Disability cash payments; Public assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

The Acting Commissioner of Social Security, Kilolo Kijakazi, having reviewed and approved this document, is delegating the authority to electronically sign this document to

[31] See Deshpande, Manasi, Tal Gross, and Yalun Su. 2021. ''Disability and Distress: The Effect of Disability Programs on Financial Outcomes.'' *American Economic Journal: Applied Economics,* 13 (2): 151–78, *https://pubs.aeaweb.org/doi/pdfplus/10.1257/app.20190709,* which found that rates of bankruptcy, foreclosure, and eviction among disability applicants are higher than in the general population; rates of these adverse financial events increase leading up to the application date and peak around the application date; and rates of these adverse financial events decline for both allowed and denied applicants after the initial disability decision, but they decline more for the allowed. This suggests that delaying the disability decision can cause long-term or permanent financial harm at a time when applicants are most vulnerable. In fact, the researchers concluded that awarding disability benefits sooner could avert a substantial amount of financial distress among applicants. *See also* Gross, T., & Trenkamp, B. (2015). Risk of Bankruptcy among Applicants to Disability Insurance. *Journal of health care for the poor and underserved, 26*(4), 1149–1156. *https://doi.org/10.1353/hpu.2015.0118,* which found that SSDI benefits decrease the risk of bankruptcy to a statistically significant degree among all age groups.

Faye I. Lipsky, who is the primary Federal Register Liaison for the Social Security Administration, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

For the reasons stated in the preamble, we are amending subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—Determining Disability and Blindness

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. In appendix 1 to subpart P of part 404:

■ a. In part A, amend section 1.00C7 by redesignating paragraphs a. and b. as b. and c., by adding a new paragraph a., and by revising newly redesignated paragraph c.; and

■ b. In part B, amend section 101.00C7 by redesignating paragraphs a. and b. as b. and c., by adding a new paragraph a., and by revising newly redesignated paragraph c.

The additions and revisions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part A

* * * * *

1.00 Musculoskeletal Disorders.

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C. * * *

7. * * *

a. The term *pandemic period* as used in 1.00C7c means the period beginning on April 2, 2021, and ending on the date that is 6 months after the effective date of a determination by the Secretary of Health and Human Services under section 319 of the Public Health Service Act, 42 U.S.C. 247d, that the national public health emergency resulting from the COVID–19 pandemic no longer exists.

* * * * *

c. For 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, and 1.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase ''within a close proximity of time'' means that *all* of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the *pandemic period.* For claims determined or decided during the *pandemic period,* all of the relevant criteria must appear in the medical record within a consecutive 12-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word ''and'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

* * * * *

Part B

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101.00 Musculoskeletal Disorders.

* * * * *

C. * * *

7. * * *

a. The term *pandemic period* as used in 101.00C7c means the period beginning on April 2, 2021, and ending on the date that is 6 months after the effective date of a determination by the Secretary of Health and Human Services under section 319 of the Public Health Service Act, 42 U.S.C. 247d, that the national public health emergency resulting from the COVID–19 pandemic no longer exists.

* * * * *

c. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase ''within a close proximity of time'' means that *all* of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the *pandemic period.* For claims determined or decided during the *pandemic period,* all of the relevant criteria must appear in the medical record within a consecutive 12-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word ''and'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

* * * * *

[FR Doc. 2021–15423 Filed 7–22–21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number: USCG–2021–0381]

Safety Zone; Recurring Events in Captain of the Port Duluth Zone—Pointe to La Pointe Swim, Bayfield, WI

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zone for the Pointe to La Pointe Swim event in Bayfield, WI, from 7 a.m. through 11 a.m. on August 7, 2021. This action is necessary to protect participants and spectators during the event. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or a designated on-scene representative.

DATES: The regulations in 33 CFR 165.943(a) will be enforced for the location listed in Table 1 to § 165.943, entry (9), from 7 a.m. through 11 a.m. on August 7, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email MST2 Jeremy Davis, telephone (218)725–3818, email *DuluthWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 165.943(a) for the location listed in Table 1 to § 165.943, entry (9), for the annual Pointe to La Pointe Swim event from 7 a.m. through 11 a.m. on August 7, 2021 on all waters between Bayfield, WI, and Madeline Island, WI, within an imaginary line created by the following coordinates: 46°48′27.55″ N, 090°48′56°.86″ W, moving southeast to 46°48′21.2″ N, 090°48′59.9″ W, moving south to 46°47′19.91″ N, 090°49′46.18″ W, moving east 46′47′21.18″ N, 090°49′02.39″ W, then moving north to 46°48′21.20″ N, 090°48′56.86″ W and finally running back to the starting point. Pursuant to 33 CFR 165.33 and 165.943(a), entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the

Captain of the Port Duluth or a designated on-scene representative. Vessels and personnel granted permission to enter the safety zone shall obey the directions of the Captain of the Port Duluth, their designated representative, or any Official Patrol displaying a Coast Guard Ensign.

This notice of enforcement is issued under authority of 33 CFR 165.943 and 5 U.S.C. 552 (a). In addition to this publication in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of the enforcement of this enforcement period via Broadcast Notice to Mariners or other suitable means. The Captain of the Port Duluth may be contacted via Channel 16, VFH–FM or at (218) 428–9357.

Dated: July 19, 2021.

F.M. Smith,

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

[FR Doc. 2021–15650 Filed 7–22–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2021–0573]

Safety Zone; Spirit Lake Dredging

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the USX Superfund Site Safety Zones: St. Louis River, and this notice of enforcement serves as a reminder to mariners this is still an enforced safety zone under Coast Guard regulations. Our regulation for safety zones within the Ninth Coast Guard District identifies this area is a regulated area within Spirit Lake Duluth, MN.

DATES: The regulations in 33 CFR 165.905(a)(1) and (2) will be enforced from August 2, 2021, through November 30, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LTJG Joseph R. McGinnis, MSU Duluth Waterways Management, U.S. Coast Guard; telephone 218–725–3818, email *D09-SMB-MSUDuluthWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the USX Superfund Site Safety Zones: St. Louis River, and this notice of enforcement serves as a reminder to mariners this is still an enforced safety zone under 33 CFR 165.905(a)(1) and (2) for the USX Superfund Site Safety Zone: St. Louis River at Safety Zone #1 (North Spirit Lake): North Boundary 46°41′33″ W, South Boundary 46°41′18″ W, East Boundary 92°11′53″ W, West Boundary 92°12′11″ W, and Safety Zone #2 (South Spirit Lake): North Boundary 46°40′45″ N, South Boundary 46°40′33″ N, East Boundary 92°11′40″ W, West Boundary 92°12′05″ W. Transit of vessels through the waters covered by these zones is prohibited. Swimming (including water skiing or other recreational use of the water which involves a substantial risk of immersion in the water) or taking of fish (including all forms of aquatic animals) from the waters covered by these safety zones is prohibited at all times. Our regulation for safety zones within the Ninth Coast Guard District identifies this area is a regulated area within Spirit Lake Duluth, MN. In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: July 19, 2021.

Frances M. Smith,

CDR, U.S. Coast Guard, Captain of the Port MSU Duluth.

[FR Doc. 2021–15651 Filed 7–22–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0248]

RIN 1625–AA00

Safety Zone; Cumberland River, Nashville, TN

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone from mile marker 190.5 to 191.5 of the Cumberland River. The safety zone is needed to protect life and the marine environment from potential hazards created by Music City Grand Prix fireworks display. This rule prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective from 9 p.m. until 10:30 p.m. on August 7, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0248 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Petty Officer Third Class Benjamin Gardner and Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615–736–5421, email *Benjamin.t.gardner@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The Coast Guard was notified of the event without ample time for the NPRM process. We must establish this safety zone by August 7, 2021, and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to ensure the safety of the participants and vessels during the Music City Grand Prix Fireworks Display on August 7, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The

Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the Music City Grand Prix Fireworks Display on August 7, 2021, will be a safety concern for anyone within a 1.0 mile radius of the fireworks barge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the Music City Grand Prix Fireworks display is occurring.

IV. Discussion of the Rule

This rule establishes a temporary safety zone on the Cumberland River, starting at mile marker 190.5 and ending at 191.5, extending from bank to bank within the river. The safety zone will be enforced from 9 p.m. to 10:30 p.m. on August 7, 2021. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the Music City Grand Prix Fireworks Display is taking place. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Cumberland River before or after the time of the events on each day. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting 1.5 hours spread over the course of 1 day that would prohibit entry within 1 mile of the fireworks barge. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0248 to read as follows:

§ 165.T08–0248 Safety Zone; Cumberland River, Nashville, TN.

(a) *Location.* The following area is a safety zone: All navigable waters of the Cumberland River from mile marker 190.5 to mile marker 191.5

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Ohio Valley (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF–FM radio channel 16 or phone at 1–800–253–7465. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement periods.* This section will be enforced from 9 p.m. until 10:30 p.m. on August 7, 2021.

Dated: July 14, 2021.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2021–15767 Filed 7–22–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0373; FRL–8715–02–R9]

Finding of Failure To Submit a State Implementation Plan To Meet the 1987 24-Hour PM_{10} Standard; Moderate Area Requirements; West Pinal County; Arizona

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is making a finding that Arizona has not submitted a required revision to the Arizona State Implementation Plan (SIP) for the West Pinal County nonattainment area addressing Clean Air Act (CAA) requirements for a Moderate area attainment plan, related rules, and other analyses needed to attain the 1987 24-hour particulate matter (PM_{10}) National Ambient Air Quality Standard (NAAQS) by December 31, 2018. Under the CAA, Arizona was required to submit a moderate area PM_{10} attainment plan for West Pinal County no later than January 2, 2014, and the State did so on December 21, 2015. On May 17, 2021, Arizona withdrew its Moderate area attainment plan submission. This finding establishes a deadline for EPA to promulgate a Federal Implementation Plan (FIP) to address these CAA requirements 24 months from the effective date of this finding. The CAA also provides for the imposition of sanctions if Arizona does not submit the required attainment plan within timeframes specified by the CAA.

DATES: This finding is effective on August 23, 2021.

ADDRESSES: The EPA has established a docket for this action identified by the following identification number, EPA–R09–OAR–2021–0373. Generally, documents in the docket for this action are available electronically at the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jerry Wamsley, EPA Region IX, (415) 947–4111, *wamsley.jerry@epa.gov.*

SUPPLEMENTARY INFORMATION: Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that an agency may issue a rule without providing notice and an opportunity for public comment when that agency finds for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. The EPA has determined that there is good cause for issuing this finding without prior proposal and opportunity for comment because there is little or no judgment involved for the EPA to make a finding of failure to submit SIPs or elements of SIPs required by the CAA, where states have not submitted a required SIP revision by the date specified by statute, made incomplete submissions, or, as in this case, withdrawn an existing submission. In such circumstances, EPA finds that notice and public procedures are unnecessary and that this constitutes good cause under 5 U.S.C. 553(b)(B).

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

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I. Background and Statutory Requirements

A. The PM_{10} NAAQS and the EPA's Nonattainment Redesignation of West Pinal County

The EPA sets the NAAQS for certain ambient air pollutants at levels required to protect public health and welfare. Particulate matter with an aerodynamic diameter less than or equal to a nominal ten micrometers, or PM_{10}, is one of the ambient air pollutants for which the EPA has established health-based standards. The EPA revised the NAAQS (or ''standards'') for particulate matter on July 1, 1987, replacing the standards for total suspended particulates (TSP

less than 30 microns in diameter) with new standards applying only to particulate matter up to 10 microns in diameter.[1] An area attains the 24-hour PM_{10} standard of 150 micrograms per cubic meter (μg/m^3) when the expected number of days per calendar year, averaged over a three year period, with a 24-hour concentration exceeding the standard (referred to as an exceedance), is equal to or less than one.[2] On January 13, 2013, the EPA announced that it was again retaining the 24-hour PM_{10} NAAQS as a 24-hour standard of 150 μg/m^3.[3]

On October 14, 2009, consistent with Section 107(d)(3)(A) of the CAA, the EPA notified the Governor of Arizona and the leaders of four Tribes with areas of Indian country either entirely or partly within Pinal County that the designation for Pinal County and nearby areas contributing to monitored violations of the PM_{10} NAAQS should be revised.[4] The EPA's initiation of the redesignation process for Pinal County was based upon our review of 2006–2008 ambient PM_{10} monitoring data from monitoring stations within the county showing widespread, frequent, and, in some cases, severe violations of the PM_{10} NAAQS.

On May 31, 2012, EPA redesignated part of Pinal County from unclassifiable to nonattainment for the 24-hour PM_{10} NAAQS, creating the West Pinal County PM_{10} nonattainment area.[5] The EPA's nonattainment redesignation of West Pinal County was based on ambient PM_{10} data collected from 2007 to 2009.[6] Our redesignation of West Pinal County to nonattainment for the PM_{10} NAAQS was effective on July 2, 2012. Consequently, under section 188(c)(1) of the CAA, Arizona was required to submit an implementation plan providing for West Pinal County's attainment of the PM_{10} NAAQS as expeditiously as practicable, but no later than the close of the sixth calendar year after redesignation, or December 31, 2018. As specified in our May 31, 2012 rulemaking, the Moderate area PM_{10} attainment plan for West Pinal County was due on January 2, 2014, 18 months after the effective date of the redesignation, as required by section 189(a)(2)(B) of the CAA.

On December 21, 2015, Arizona submitted ''The 2015 West Pinal Moderate PM_{10} Nonattainment Area SIP'' (Moderate Area Plan) with related rules and analyses for West Pinal County.[7] The submission included rules regulating PM_{10} emissions from construction sites, crop operations, animal operations, irrigation districts, and general fugitive dust. On May 1, 2017, the EPA approved the submitted rules regulating PM_{10} emissions from construction sites, crop operations, irrigation districts, and general fugitive dust, but did not act on the remainder of the submission.[8]

On June 24, 2020, the EPA determined that the West Pinal County nonattainment area had not attained the 1987 24-hour PM_{10} NAAQS by the latest permissible December 31, 2018 attainment date and reclassified the area from Moderate to Serious.[9] The EPA's finding of failure to attain the NAAQS by the required date and concomitant reclassification established an 18-month deadline for Arizona to submit a Serious area attainment plan for the West Pinal County PM_{10} nonattainment area by January 24, 2022.

On January 8, 2021, the EPA proposed a partial approval and partial disapproval of the Moderate Area Plan, proposing to disapprove all elements of the attainment plan, except the emissions inventories.[10] Subsequently, on February 26, 2021, we proposed a limited approval and limited disapproval of statutory provisions and rules that govern particulate matter emissions from agricultural activity that Arizona submitted with the plan.[11]

On May 17, 2021, ADEQ withdrew all submitted portions of the Moderate Area Plan that the EPA had not approved previously into the SIP.[12] In addition to the required attainment plan, Arizona's withdrawal action included the agricultural dust regulations that the EPA had not already approved into the SIP. Because Arizona has withdrawn the submission, the State has failed to meet its obligation to submit an attainment plan for the Moderate area attainment plan requirements for the West Pinal County PM_{10} nonattainment area, providing the basis for this finding.

B. CAA Moderate PM10 Nonattainment Area Requirements for West Pinal County

Areas redesignated as nonattainment are subject to the applicable requirements of part D, title I of the CAA and are classified as Moderate by operation of law, consistent with section 188(a) of the CAA. Within 18 months of the effective date of the redesignation, *i.e.,* by January 2, 2014, Arizona was required to submit an attainment plan to the EPA providing for how the State will meet the PM_{10} NAAQS within the West Pinal County nonattainment area no later than December 31, 2018. Among other things, this Moderate area attainment plan must contain statutorily mandated elements and, according to the CAA and EPA guidance, address the following requirements: (1) An approved permit program for construction of new and modified major stationary sources; [13] (2) a demonstration that the plan provides for attainment by no later than the applicable Moderate area attainment date or a demonstration that attainment by that date is impracticable; [14] (3) provisions for the implementation of reasonably available control measures (RACM) and reasonably available control technology (RACT); [15] (4) quantitative milestones that will be used to evaluate compliance with the requirement to demonstrate reasonable further progress (RFP); [16] (5) evaluation and regulation of PM_{10} precursors; [17] (6) a description of the expected annual incremental reductions in emissions that will demonstrate RFP; [18] (7) emissions inventories, as necessary; [19] (8) other control measures besides RACM and RACT as may be needed for

[1] 53 FR 24634 (July 1, 1987). The 1987 PM_{10} standards included a 24-hour (150 micrograms per cubic meter (μg/m^3)) and an annual standard (50 μg/m^3). In 2006, the EPA revoked the annual standard; see 71 FR 61144 (October 17, 2006) and 40 CFR 50.6.

[2] An exceedance is defined as a daily value that is above the level of the 24-hour standard, 150 μg/m^3, after rounding to the nearest 10 μg/m^3 (*i.e.,* values ending in five or greater are to be rounded up). Consequently, a recorded value of 154 μg/m^3 would not be an exceedance because it would be rounded to 150 μg/m^3; whereas, a recorded value of 155 μg/m^3 would be an exceedance because it would be rounded to 160 μg/m^3. See 40 CFR part 50, appendix K, section 1.0.

[3] 78 FR 3806 (January 13, 2013).

[4] Letter from Laura Yoshii, Acting Regional Administrator, to Governor of Arizona Jan Brewer dated October 14, 2009. By letters dated December 30, 2009, the EPA notified the tribal leaders of the Ak-Chin Indian Community, Gila River Indian Community, and San Carlos Apache Tribe. The EPA notified Tohono O'odham Nation by letter dated September 21, 2010.

[5] For the boundaries of the West Pinal County PM_{10} nonattainment area, see 40 CFR 81.303. Also, for a detailed discussion of these boundaries, see our final rule at 77 FR 32024 (May 31, 2012) and proposed rule at 75 FR 60680 (October 1, 2010). No areas of Indian country are located in the West Pinal PM_{10} nonattainment area.

[6] 75 FR 60680 (October 1, 2010).

[7] Letter dated December 21, 2015 from Eric C. Massey, Director, Air Quality Division, ADEQ to Jared Blumenfeld, Regional Administrator, EPA Region IX.

[8] 82 FR 20267 (May 1, 2017).

[9] 85 FR 37756 (June 24, 2020).

[10] 86 FR 1347 (January 8, 2021).

[11] 86 FR 11681 (February 26, 2021).

[12] Letter from Daniel Czecholinski, Arizona Department of Environmental Quality, to Deborah Jordan, EPA Region IX, dated May 17, 2021.

[13] CAA section 189(a)(1)(A).

[14] CAA section 189(a)(1)(B).

[15] CAA section 189(a)(1)(C).

[16] CAA section 189(c).

[17] CAA section 189(e).

[18] CAA section 172(c)(2).

[19] CAA section 172(c)(3).

attainment; [20] (9) contingency measures; [21] and (10) a motor vehicle emissions budget for the purpose of determining the conformity of transportation programs and plans developed by state transportation agencies.[22] With Arizona's May 17, 2021 withdrawal action, the State has failed to meet its obligation to submit nine of the ten required Moderate area attainment plan elements; today's action does not affect ADEQ's permit program governing the construction and operation of new and modified major stationary sources of PM_{10} within the West Pinal County nonattainment area.[23]

By this action, the EPA is finding that Arizona failed to submit the nine required PM_{10} Moderate Area attainment plan elements for the West Pinal County PM_{10} nonattainment area listed above. As noted, Arizona has submitted a major source PM_{10} permitting program including West Pinal County and that element is not a subject of this finding.

C. Consequences of This Finding That Arizona Failed To Submit a PM_{10} Implementation Plan for West Pinal County

The EPA is finding that Arizona has failed to make a required Moderate area attainment plan submission for the 1987 PM_{10} NAAQS for the West Pinal County area, except for the permit program required under section 189(a)(1)(A). With this finding, section 179 of the CAA starts a sanctions clock and a FIP clock. Section 179(a) of the CAA specifies the consequences for a state if the EPA finds that a state has failed to make a required SIP submission, if the EPA has determined that a submitted SIP is incomplete, or if the EPA has disapproved a SIP submission. If the EPA has not affirmatively determined that Arizona has made complete submissions of the required nonattainment SIP elements within 18 months of the effective date of this action, then the offset sanction identified in section 179(b)(2) will apply to West Pinal County, pursuant to section 179(a) and (b) and 40 CFR 52.31. If the EPA has not affirmatively determined that Arizona has made a complete SIP submission for West Pinal County within six months after imposition of this offset sanction, then the highway funding sanction will be imposed, as required under section 179(b)(1) of the CAA and 40 CFR 52.31.

Arizona may avoid these sanctions by taking timely action to remedy this finding. The 18-month clock governing the Act's imposition of sanctions on Arizona will stop and sanctions will not take effect if the EPA finds that the State has made a complete SIP submission for the Moderate area attainment plan requirements for the West Pinal County area within 18 months of the date of this finding. Similarly, the EPA is not required to promulgate a FIP if Arizona makes the required SIP submission and the EPA takes final action to approve the submission within two years of the finding of failure to submit a required SIP. In sum, the CAA does not require sanctions or a FIP if the State and the EPA take timely action to remedy this finding.

As discussed previously, the EPA determined that West Pinal County did not meet the PM_{10} NAAQS by December 31, 2018, causing West Pinal County to be reclassified, by operation of law, from a Moderate to a Serious PM_{10} nonattainment area. With this reclassification of West Pinal County to Serious, Arizona is required to submit, by January 24, 2022, a nonattainment plan SIP revision that complies with the statutory and regulatory requirements for Serious PM_{10} nonattainment plans and that demonstrates attainment of the PM_{10} NAAQS as expeditiously as practicable, but no later than December 31, 2022. Although reclassification of West Pinal County from Moderate to Serious does not eliminate Arizona's obligation to meet Moderate area nonattainment plan requirements, the EPA anticipates that Arizona's submission of an approvable Serious area nonattainment plan would also satisfy the State's Moderate area nonattainment plan obligations.[24] Therefore, should Arizona submit a complete Serious area attainment plan for the West Pinal County PM_{10} nonattainment area, the sanction clocks associated with this finding of failure to submit would stop. Similarly, should Arizona submit, and the EPA subsequently approve, a Serious area attainment plan for the West Pinal County PM_{10} nonattainment area, such a final approval action would stop the FIP clock associated with this finding of failure to submit the Moderate area implementation plan elements.

II. Final Action

The EPA finds that Arizona has not submitted a revision to the Arizona SIP addressing CAA requirements for a Moderate area attainment plan, related rules, and other analyses, for the West Pinal County PM_{10} nonattainment area. Under provisions of the CAA, Arizona was required to submit a Moderate area PM_{10} implementation plan for West Pinal County no later than January 2, 2014. Although Arizona submitted a Moderate area PM_{10} attainment plan, related rules, and analyses, on December 21, 2015, the State withdrew this submittal on May 17, 2021, giving rise to this finding.

This finding of failure to submit the required Moderate area PM_{10} attainment plan establishes a deadline, 24 months after the effective date of this finding, for EPA to promulgate a FIP to address the CAA requirements for a Moderate area PM_{10} attainment plan, unless prior to this deadline, Arizona submits and the EPA approves the State's Moderate area PM_{10} attainment plan as meeting all the requirements of the CAA. The CAA also provides for the imposition of emissions offset sanctions 18 months from the effective date of this finding and highway funding sanctions 24 months from the effective date of this finding, if Arizona does not submit the required complete Moderate area PM_{10} attainment plan before these deadlines.

III. Statutory and Executive Order Reviews

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

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

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

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities beyond those imposed by state law.

[20] CAA section 172(c)(6).

[21] CAA section 172(c)(9).

[22] 40 CFR 93.102(b)(1).

[23] For a discussion of our action on Arizona's submittal to meet CAA section 189(a)(1)(A), see 80 FR 67319 (November 2, 2015).

[24] See section 189(b)(1), specifying that Serious Area plan requirements include ''the provisions submitted to meet the requirements of paragraph (a)(1) [of section 189] (relating to Moderate Areas).''

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, will result from this action.

E. Executive Order 13132: Federalism

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

F. Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because this action does apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on tribal governments or preempt tribal law. There are no areas of Indian country located in the West Pinal PM_{10} nonattainment area. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not impose additional requirements beyond those imposed by state law.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

The EPA lacks the discretionary authority to address environmental justice in this action.

K. Congressional Review Act (CRA)

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

L. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 21, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: July 8, 2021.

Elizabeth Adams,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–15667 Filed 7–22–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2020–0221; FRL–8761–02–R4]

Air Plan Approval; Tennessee; Knoxville Area Limited Maintenance Plan for the 1997 8-Hour Ozone NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a state implementation plan (SIP) revision submitted by the State of Tennessee, through the Tennessee Department of Environment and Conservation (TDEC), Air Pollution Control Division, via a letter dated January 23, 2020. The SIP revision includes the 1997 8-hour ozone national ambient air quality standards (NAAQS) Limited Maintenance Plan (LMP) for the Knoxville, Tennessee Area (hereinafter referred to as the ''Knoxville Area'' or ''Area''). The Knoxville Area, as defined in this action, is comprised of Jefferson, Loudon, and Sevier Counties in their entireties, the portion of Cocke County that falls within the boundary of the Great Smoky Mountains National Park, and a portion of Anderson County that excludes the area surrounding Tennessee Valley Authority (TVA) Bull Run Fossil Plant. EPA is approving the Knoxville Area LMP because it provides for the maintenance of the 1997 8-hour ozone NAAQS within the Knoxville Area through the end of the second 10-year portion of the maintenance period. The effect of this action is to make certain commitments related to maintenance of the 1997 8-hour ozone NAAQS in the Knoxville Area federally enforceable as part of the Tennessee SIP.

DATES: This rule is effective August 23, 2021.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R04–OAR–2020–0221. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials can either be retrieved electronically via *www.regulations.gov* or in hard copy at the Air Regulatory

Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sarah LaRocca, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8994. Ms. LaRocca can also be reached via electronic mail at *larocca.sara@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1979, under section 109 of the Clean Air Act (CAA or Act), EPA established primary and secondary NAAQS for ozone at 0.12 parts per million (ppm), averaged over a 1-hour period. *See* 44 FR 8202 (February 8, 1979). On July 18, 1997, EPA revised the primary and secondary NAAQS for ozone to set the acceptable level of ozone in the ambient air at 0.08 ppm, averaged over an 8-hour period. *See* 62 FR 38856 (July 18, 1997).[1] EPA set the 8-hour ozone NAAQS based on scientific evidence demonstrating that ozone causes adverse health effects at lower concentrations and over longer periods of time than was understood when the pre-existing 1-hour ozone NAAQS was set. EPA determined that the 8-hour ozone NAAQS would be more protective of human health, especially children and adults who are active outdoors, and individuals with a pre-existing respiratory disease, such as asthma.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the nation as attaining or not attaining the NAAQS. On April 15, 2004, EPA designated the Knoxville 1997 NAAQS Area, which is comprised of Anderson, Blount, Knox, Jefferson, Loudon, and Sevier Counties in their entireties, and the portion of Cocke County that falls within the boundary of the Great Smoky Mountains National Park, as nonattainment for the 1997 8-hour ozone NAAQS, and the designation became effective on June 15, 2004. *See* 69 FR 23858 (April 30, 2004). Similarly, on May 21, 2012, EPA designated areas as unclassifiable/attainment or nonattainment for the 2008 8-hour ozone NAAQS. EPA designated Blount and Knox Counties and the portion of Anderson County surrounding the TVA Bull Run Fossil Plant as nonattainment for the 2008 8-hour ozone NAAQS and classified as a marginal nonattainment area (hereinafter referred to as the ''Knoxville 2008 NAAQS Area''). This designation became effective on July 20, 2012.[2] In addition, on November 16, 2017, areas were designated for the 2015 8-hour ozone NAAQS. The Knoxville 1997 NAAQS Area[3] was designated attainment/unclassifiable for the 2015 8-hour ozone NAAQS, with an effective date of January 16, 2018.[4]

A state may submit a request to redesignate a nonattainment area that is attaining a NAAQS to attainment, and, if the area has met other required criteria described in section 107(d)(3)(E) of the CAA, EPA may approve the redesignation request.[5] One of the criteria for redesignation is to have an approved maintenance plan under CAA section 175A. The maintenance plan must demonstrate that the area will continue to maintain the NAAQS for the period extending ten years after redesignation, and it must contain such additional measures as necessary to ensure maintenance and such contingency provisions as necessary to assure that violations of the NAAQS will be promptly corrected. Eight years after the effective date of redesignation, the state must also submit a second maintenance plan to ensure ongoing maintenance of the NAAQS for an additional ten years pursuant to CAA section 175A(b) (*i.e.,* ensuring maintenance for 20 years after redesignation).

EPA has published long-standing guidance for states on developing maintenance plans.[6] The Calcagni memo provides that states may generally demonstrate maintenance by either performing air quality modeling to show that the future mix of sources and emission rates will not cause a violation of the NAAQS or by showing that projected future emissions of a pollutant and its precursors will not exceed the level of emissions during a year when the area was attaining the NAAQS (*i.e.,* attainment year inventory). *See* Calcagni memo at page 9. EPA clarified in three subsequent guidance memos that certain areas could meet the CAA section 175A requirement to provide for maintenance by showing that the area was unlikely to violate the NAAQS in the future, using information such as the area's design value[7] being significantly below the standard and the area having a historically stable design value.[8] EPA refers to a maintenance plan containing this streamlined demonstration as an LMP.

EPA has interpreted CAA section 175A as permitting the LMP option because section 175A of the Act does not define how areas may demonstrate maintenance, and in EPA's experience implementing the various NAAQS, areas that qualify for an LMP and have approved LMPs have rarely, if ever, experienced subsequent violations of the NAAQS. As noted in the LMP guidance memoranda, states seeking an LMP must still submit the other maintenance plan elements outlined in the Calcagni memo, including: An attainment emissions inventory, provisions for the continued operation of the ambient air quality monitoring network, verification of continued attainment, and a contingency plan in the event of a future violation of the NAAQS. Moreover, a state seeking an LMP must still submit its section 175A maintenance plan as a revision to its SIP, with all attendant notice and comment procedures. While the LMP

[1] In March 2008, EPA completed another review of the primary and secondary ozone NAAQS and tightened them further by lowering the level for both to 0.075 ppm. *See* 73 FR 16436 (March 27, 2008). Additionally, in October 2015, EPA completed a review of the primary and secondary ozone NAAQS and tightened them by lowering the level for both to 0.070 ppm. *See* 80 FR 65292 (October 26, 2015).

[2] *See* 77 FR 30088.

[3] The ''Knoxville 1997 NAAQS Area'' encompasses both the ''Knoxville Area'' and the ''Knoxville 2008 NAAQS Area''.

[4] *See* 82 FR 54232 (November 16, 2017).

[5] Section 107(d)(3)(E) of the CAA sets out the requirements for redesignating a nonattainment area to attainment. They include attainment of the NAAQS, full approval of the applicable SIP pursuant to CAA section 110(k), determination that improvement in air quality is a result of permanent and enforceable reductions in emissions, demonstration that the state has met all applicable section 110 and part D requirements, and a fully approved maintenance plan under CAA section 175A.

[6] John Calcagni, Director, Air Quality Management Division, EPA Office of Air Quality Planning and Standards (OAQPS), ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' September 4, 1992 (Calcagni memo).

[7] The ozone design value for a monitoring site is the 3-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations. The design value for an ozone area is the highest design value of any monitoring site in the area.

[8] *See* ''Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas'' from Sally L. Shaver, OAQPS, dated November 16, 1994; ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' from Joseph Paisie, OAQPS, dated October 6, 1995; and ''Limited Maintenance Plan Option for Moderate PM_{10} Nonattainment Areas'' from Lydia Wegman, OAQPS, dated August 9, 2001. Copies of these guidance memoranda can be found in the docket for this proposed rulemaking.

guidance memoranda were originally written with respect to certain NAAQS,[9] EPA has extended the LMP interpretation of section 175A to other NAAQS and pollutants not specifically covered by the previous guidance memos.[10]

In a notice of proposed rulemaking (NPRM) published on June 11, 2021 (86 FR 31218), EPA proposed to approve Tennessee's LMP because the State made a showing, consistent with EPA's prior LMP guidance, that the Area's ozone concentrations are well below the 1997 8-hour ozone NAAQS and have been historically stable and that it met the other maintenance plan requirements. The details of Tennessee's submission and the rationale for EPA's action are explained in the proposed rulemaking. Comments on the June 11, 2021, NPRM were due on or before July 12, 2021. EPA did not receive any comments on the June 11, 2021, NPRM.

II. Final Action

EPA is taking final action to approve the Knoxville Area LMP for the 1997 8-hour ozone NAAQS, submitted by TDEC on January 23, 2021, as a revision to the Tennessee SIP. EPA is approving the Knoxville Area LMP because it includes a sufficient update of the various elements of the 1997 8-hour ozone NAAQS Maintenance Plan approved by EPA for the first 10-year portion of the maintenance period (including emissions inventory, assurance of adequate monitoring and verification of continued attainment, and contingency provisions) and retains the relevant provisions of the SIP under sections 110(k) and 175A of the CAA.

EPA also finds that the Knoxville Area qualifies for the LMP option and that the Knoxville Area LMP is sufficient to provide for maintenance of the 1997 8-hour ozone NAAQS in the Knoxville Area over the second 10-year maintenance period (*i.e.,* through 2031).

III. Statutory and Executive Order Reviews

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

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

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 21, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

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

Dated: July 15, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.2220, amend the table in paragraph (e) by adding, at the end of the table, the entry ''1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Knoxville, Tennessee Area'' to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

[9] The prior memos addressed: Unclassifiable areas under the 1-hour ozone NAAQS, nonattainment areas for the PM_{10} (particulate matter with an aerodynamic diameter less than 10 microns) NAAQS, and nonattainment for the carbon monoxide (CO) NAAQS.

[10] *See, e.g.,* 79 FR 41900 (July 18, 2014) (approval of the second ten-year LMP for the Grant County 1971 SO_2 maintenance area).

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
*	* * *	*	*	*
1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Knoxville, Tennessee Area.	Jefferson, Loudon, and Sevier Counties in their entireties, the portion of Cocke County that falls within the boundary of the Great Smoky Mountains National Park, and a portion of Anderson County that excludes the area surrounding Tennessee Valley Authority (TVA) Bull Run Fossil Plant.	1/8/2020	7/23/2021, [Insert citation of publication].	

[FR Doc. 2021–15535 Filed 7–22–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–151; RM–11898; DA 21–767; FR ID 36877]

Television Broadcasting Services Eugene, Oregon

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On April 14, 2021, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by Sinclair Eugene Licensee, LLC (Petitioner), the licensee of KVAL–TV, channel 13 (CBS), Eugene, Oregon, requesting the substitution of channel 28 for channel 13 at Eugene in the DTV Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends FCC regulations to substitute channel 28 for channel 13 at Eugene.

DATES: Effective July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Andrew Manley, Media Bureau, at (202) 418–0596 or *Andrew.Manley@fcc.gov*.

SUPPLEMENTARY INFORMATION: The proposed rule was published at 86 FR 22126 on April 27, 2021. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 28. No other comments were filed. The Petitioner states that VHF channels have certain propagation characteristics which may cause reception issues for some viewers. In addition, KVAL has received numerous complaints from viewers unable to receive the Station's over-the-air signal, despite being able to receive signals from other stations. The Petitioner also demonstrated that while the noise limited contour of the proposed channel 28 facility does not completely encompass the licensed channel 13 contour, KVAL is a CBS affiliate and there are three other CBS affiliated stations that, together, overlap all areas where the channel 28 noise limited contour does not extend beyond the channel 13 noise limited contour, except in a small geographic area with no population. Thus, there is no loss of CBS network service.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 21–151; RM–11898; DA 21–767, adopted July 2, 2021, and released July 2, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(i), amend the Post-Transition Table of DTV Allotments, under Oregon, by revising the entry for Eugene to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
OREGON	
* * * * *	
Eugene	9, 17, 28, *29, 31.
* * * * *	

[FR Doc. 2021–15691 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–176; RM–11903; DA 21–846; FR ID 39244]

Television Broadcasting Services Missoula, Montana

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On April 21, 2021, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by Sinclair Media, LLC (Petitioner), the licensee of KECI–TV, channel 13 (NBC), Missoula, Montana, requesting the substitution of channel 20 for channel 13 at Missoula in the DTV Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends FCC regulations to substitute channel 20 for channel 13 at Missoula.

DATES: Effective July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: The proposed rule was published at 86 FR 22929 on April 30, 2021. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 20. No other comments were filed. The Petitioner states that VHF channels have certain propagation characteristics which may cause reception issues for some viewers. In addition, KECI–TV has received numerous complaints from viewers unable to receive the Station's over-the-air signal, despite being able to receive signals from other stations. While the proposed channel 20 noise limited contour does not completely encompass the relevant channel 13 noise limited contour, Petitioner demonstrated there would be a loss of service to only 65 people, a number the Commission considers *de minimis.* In addition, KECI–TV's proposed channel 20 facility is predicted to serve a total of 252,689 persons, a net gain of 38,879 potential viewers over the existing KECI–TV channel 13 facility. As the Bureau explained in the *NPRM,* it used the technical parameters of KECI–TV's original post-transition digital channel 13 facility (File No. BPCDT–20080327AFR) in determining any predicted loss which may occur.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 21–176; RM–11903; DA 21–846, adopted July 15, 2021, and released July 16, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(i), amend the Post-Transition Table of DTV Allotments, under Montana, by revising the entry for Missoula to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
Montana	
Missoula	7, *11, 17, 20, 23
* * * * *	

[FR Doc. 2021–15690 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–219; RM–11907; DA 21–844; FR ID 39360]

Television Broadcasting Services Quincy, Illinois

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On May 17, 2021, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by WGEM License, LLC (Petitioner), the licensee of WGEM–TV, channel 10 (NBC), Quincy, Illinois, requesting the substitution of channel 19 for channel 10 at Quincy in the DTV Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends FCC regulations to substitute channel 19 for channel 10 at Quincy.

DATES: Effective July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov*.

SUPPLEMENTARY INFORMATION: The proposed rule was published at 86 FR 28523 on May 27, 2021. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 19, and Gray Television, Inc. filed comments in support. The Petitioner states that VHF channels have certain propagation characteristics which may cause reception issues for some viewers. In addition, WGEM–TV has received numerous complaints from viewers unable to receive the Station's over-the-air signal. In addition, the Petitioner demonstrated that while the proposed channel 19 facility will result in a slight reduction in WGEM–TV's noise limited contour, use of the Longley-Rice propagation model indicates that the proposed channel 19 facility will have an extended terrain-limited service throughout the gap area, and thus, there will be no loss of service.

This is a synopsis of the Commission's *Report and Order,* MB

Docket No. 21–219; RM–11907; DA 21–844, adopted July 15, 2021, and released July 16, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(i), amend the Post-Transition Table of DTV Allotments, under Illinois, by revising the entry for Quincy to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
ILLINOIS	
Quincy	19, 32, *34.
* * * * *	

[FR Doc. 2021–15692 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–177; RM–11904; DA 21–848; FR ID 39235]

Television Broadcasting Services Redding, California

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On April 21, 2021, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by Sinclair Media Licensee, LLC (Petitioner), the licensee of KRCR–TV, channel 7 (ABC), Redding, California, requesting the substitution of channel 15 for channel 7 at Redding in the DTV Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends FCC regulations to substitute channel 15 for channel 7 at Redding.

DATES: Effective July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: The proposed rule was published at 86 FR 25978 on May 12, 2021. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 15. No other comments were filed. The Petitioner states that VHF channels have certain propagation characteristics which may cause reception issues for some viewers. In addition, KRCR has received numerous complaints from viewers unable to receive the Station's over-the-air signal, despite being able to receive signals from other stations. The Petitioner also submitted an analysis, using the Commission's *TVStudy* software analysis program, demonstrating that the proposed channel change from channel 7 to channel 15 would result in a substantial increase in signal receivability for KRCR's core viewers, with a minimal loss of service to only 299 people, a number the Commission considers *de minimis.*

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 21–177; RM–11904; DA 21–848, adopted July 15, 2021, and released July 16, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(i), amend the Post-Transition Table of DTV Allotments, under California, by revising the entry for Redding to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.

Community	Channel No.
* * * * *	
California	
* * * * *	
Redding	* 9, 15
* * * * *	

[FR Doc. 2021–15687 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–185; RM–11906; DA 21–847; FR ID 39219]

Television Broadcasting Services Butte, Montana

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On April 26, 2021, the Media Bureau, Video Division (Bureau) issued a *Notice of Proposed Rulemaking* (*NPRM*) in response to a petition for rulemaking filed by Sinclair Media Licensee, LLC (Petitioner), the licensee of KTVM–TV (NBC), channel 6, Butte, Montana, requesting the substitution of channel 20 for channel 6 at Butte in the DTV Table of Allotments. For the reasons set forth in the *Report and Order* referenced below, the Bureau amends FCC regulations to substitute channel 20 for channel 6 at Butte.

DATES: Effective July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647 or *Joyce.Bernstein@fcc.gov.*

SUPPLEMENTARY INFORMATION: The proposed rule was published at 88 FR 24837 on May 10, 2021. The Petitioner filed comments in support of the petition reaffirming its commitment to apply for channel 20. REC Networks also filed comments. The Petitioner states that VHF channels have certain propagation characteristics which may cause reception issues for some viewers. In addition, KTVM–TV has received numerous complaints from viewers unable to receive the Station's over-the-air signal, despite being able to receive signals from other stations. While the proposed channel 20 noise limited contour does not completely encompass the relevant channel 6 noise limited contour, KTVM–TV is an NBC affiliate and there are two other NBC affiliated stations that serve some portion of the loss area. In addition, the Petitioner submitted an analysis, using the Commission's *TVStudy* software analysis program, demonstrating that, after taking into account service provided by other NBC stations, all of the population located within KTVM–TV's original post-DTV transition channel 6 noise limited contour will continue to receive NBC service, except for 66 people, a number the Commission considers *de minimis.* As the Bureau explained in the *NPRM,* it used the technical parameters of KTVM–TV's original post-transition digital channel 6 facility (File Nos. BPCDT–20080314ADF; BLCDT–20090622ADT) in determining any predicted loss which may occur.

This is a synopsis of the Commission's *Report and Order,* MB Docket No. 21–185; RM–11906; DA 21–847 adopted July 15, 2021 and released July 16, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs.* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 155, 301, 303, 307, 309, 310, 334, 336, 339.

■ 2. In § 73.622(i), amend the Post-Transition Table of DTV Allotments, under Montana, by revising the entry for Butte to read as follows:

§ 73.622 Digital television table of allotments.

* * * * *

(i) * * *

Community	Channel No.
* * * * *	
Montana	
* * * * *	
Butte	5, 19, 20, 24
* * * * *	

[FR Doc. 2021–15689 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 384

[Docket No. FMCSA–2020–0198]

RIN 2126–AC36

Commercial Driver's License Standards, Requirements and Penalties; Exclusively Electronic Exchange of Driver History Record Information

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FMCSA codifies the statutory requirement that State driver licensing agencies (SDLAs) implement a system and practices for the exclusively electronic exchange of driver history record (DHR) information through the Commercial Driver's License Information System (CDLIS), including the posting of convictions, withdrawals, and disqualifications. The rule aligns FMCSA's regulations with existing statutory requirements set forth in the Moving Ahead for Progress in the 21st Century Act (MAP–21). The rule also establishes a date by which States must be in substantial compliance with this final rule.

DATES:

Effective Date: This final rule is effective August 23, 2021.

Compliance Date: Compliance with the final rule is required August 22, 2024.

Petitions for Reconsideration: Petitions for reconsideration of this final rule must be submitted to the FMCSA Administrator no later than August 23, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Joshua Jones, Commercial Driver's License Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–7332, *cdlcompliance@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Availability of Rulemaking Documents

For access to docket FMCSA–2020–0198 to read background documents, go to *https://www.regulations.gov/docket/FMCSA-2020-0198/document* at any time, or to Dockets Operations at U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

II. Executive Summary

This rule revises 49 CFR 384.208, Notification of disqualification, and 384.209, Notification of traffic violations, to require that States implement a system and practices for the exclusively electronic exchange of DHR information through CDLIS, including the posting of convictions, withdrawals, and disqualifications. The requirements are mandated by sections 32305(a)(1) and 32305(b)(1)(B) of MAP–21 (Pub. L. 112–141, 126 Stat. 405, 792, codified at 49 U.S.C. 31309(e)(4)(A)(ii) and 31311(a)(23)). The purpose of the rule is to align FMCSA's regulations with existing statutory requirements. States must achieve substantial compliance with this requirement as soon as practicable, but not later than 3 years after the effective date of the final rule. ''Substantial compliance'' means that a State meets this requirement ''by means of the demonstrable combined effect of its statutes, regulations, administrative procedures and practices, organizational structures, internal control mechanisms, resource assignments (facilities, equipment, and personnel), and enforcement practices.'' 49 CFR 384.301(a).

Because all States currently have the technical capability to send DHR information electronically through CDLIS, including convictions, withdrawals, and disqualifications, the Agency does not expect this rule to result in incremental costs or benefits to the States. Costs and benefits are discussed further below in Section VI.

III. Legal Basis for the Rulemaking

This final rule is based on the general authority of 49 U.S.C. chapter 313. The provisions in 49 U.S.C. chapter 313, implemented in 49 CFR parts 383 and 384, establish the commercial driver's license (CDL) and commercial learner's permit (CLP) programs, as well as the CDLIS. The CDLIS is a national information technology system facilitating the electronic exchange of driver-specific data among the States, including commercial license status and driving history (49 U.S.C. 31309). The States are required to ensure that CDL and CLP holders convicted of serious traffic violations are prohibited from operating a CMV for the periods prescribed (49 U.S.C. 31310). The Secretary of Transportation (the Secretary) is directed to monitor the States' compliance with the licensing, testing, and qualification standards set forth in the statute (49 U.S.C. 31311). The goal of these provisions is to improve highway safety by ensuring that drivers of large trucks and buses are qualified to operate those vehicles, and to remove unqualified drivers from public roads.

As noted above, this final rule derives from the specific authority of sections 32305(a)(1) and 32305(b)(1)(B) of MAP–21. Those provisions require, respectively, that States use CDLIS to receive and submit driver conviction and disqualification data, and that, to avoid having apportionments from the Highway Trust Fund under 23 U.S.C. 104(b)(1) and (b)(2) withheld, States must implement procedures for the exclusively electronic exchange of DHR information on CDLIS, including the posting of convictions, withdrawals, and disqualifications. This final rule incorporates those requirements into the Code of Federal Regulations (CFR).

The Administrative Procedure Act (APA) provides that notice and comment are not required when the agency finds ''good cause'' to dispense with such procedures, and incorporates the finding, and a brief statement of reasons supporting the finding, in the rule issued. Good cause exists when the agency determines that notice and public comment procedures ''are impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)). In this case, Congress did not vest any discretion in the Secretary for carrying out the statutory provisions cited above; these requirements are already in effect and enforceable, regardless of whether they are incorporated in the CFR. The Agency therefore finds that notice and public comment are unnecessary because FMCSA is not authorized to make any changes in these requirements in response to public comments. This final rule simply codifies an existing statutory requirement, thereby aligning the statute and CFR.

The requirements pertaining to public participation in rulemaking, as set forth in 49 U.S.C. 31136(g) and 49 CFR 389.13(b), do not apply here because this final rule is not a major rule.[1]

Finally, the FMCSA Administrator is delegated authority under 49 CFR 1.87(e)(1) to carry out the functions vested in the Secretary by 49 U.S.C. chapter 313, relating to commercial motor vehicle operators.

IV. Discussion of Final Rule

As noted above, MAP–21 amended 49 U.S.C. 31311(a) by adding the requirement that States implement a system and practices for the exclusively electronic exchange of driver history record information on the system the Secretary maintains under section 31309 (*i.e.,* CDLIS), including the posting of convictions, withdrawals, and disqualifications. This final rule codifies those requirements.

In March 2020, FMCSA held an information listening session during its regular ''Roundtable'' discussion with the American Association of Motor Vehicle Administrators (AAMVA), SDLAs, and other stakeholders affected by the electronic exchange requirements. While all States currently have the technical capability to transmit the DHR information through CDLIS, some SDLAs are unable to do so when the driver information (*e.g.,* driver's CDL number, date of birth, or State of record), required for CDLIS to validate and accept the electronic record, is incorrect or missing. Under those circumstances, States must rely on alternative methods of transmission, such as the U.S. mail. Some States also noted the need for specific authorization by their State legislatures to incorporate

[1] ''A ''major rule'' means any rule that the Administrator of Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) finds has resulted in or is likely to result in (a) an annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, geographic regions, or Federal, State, or local government agencies; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets (49 CFR 389.3).

the exclusively electronic exchange requirements into State law.

In recognition of these issues, the final rule provides that States should achieve substantial compliance as soon as possible, but not later than 3 years from the effective date of this rule. This period provides sufficient time for those SDLAs required to obtain authorization from their State legislatures to do so. In addition, FMCSA will work closely with AAMVA and the States to address current systemic impediments to transmitting DHR information through CDLIS, and to provide related regulatory guidance responding to SDLAs' questions and concerns. The Agency acknowledges that some SDLAs believe CDLIS is not the most efficient electronic means of transmitting driver conviction information. As discussed above, however, FMCSA must adhere to the statutory requirements codified by this final rule, which specify that CDLIS be used to transmit the information.

V. Section-by-Section Analysis

The words ''via CDLIS'' are added to the end of paragraph (a) of § 384.208. The phrase ''and must be transmitted through CDLIS'' is added to the end of paragraph (c) of § 384.209.

This final rule also adds new paragraph (n) to § 384.301, requiring States to come into substantial compliance with the changes made by this final rule within 3 years of its effective date.

VI. Regulatory Analyses

A. Executive Order (E.O.) 12866 (Regulatory Planning and Review), E.O. 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

FMCSA has considered the impact of this final rule under E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and DOT's regulatory policies and procedures. OIRA determined that this final rule is not a significant regulatory action under section 3(f) of E.O. 12866, as supplemented by E.O. 13563, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. Accordingly, OMB has not reviewed it under these orders.

This rulemaking codifies a mandate imposed by MAP–21, as set forth in 49 U.S.C. 31309(e)(4)(A)(ii) and 31311(a)(23). Those provisions require, respectively, that States use CDLIS to receive and submit driver conviction and disqualification data, and that, to avoid having apportionments from the Highway Trust Fund under 23 U.S.C. 104(b)(1) and (b)(2) withheld, States must implement procedures for the exclusively electronic exchange of DHR information on CDLIS, including the posting of convictions, withdrawals, and disqualifications.

While all States currently have the technical capability to comply with the MAP–21 requirements by electronically transmitting DHR information through CDLIS, some States must rely on non-electronic means (*e.g.,* mail) to transfer the DHR information on those occasions when they do not have sufficient information for CDLIS to validate and accept transmission (*e.g.,* when there is a missing or incorrect date of birth or incorrect CDL number). As discussed above, FMCSA will work with AAMVA and the States to address the CDLIS constraints on submitting electronic DHR information, which should minimize the extent to which the initiating State is unable to complete the transmission due to deficient information, and to streamline further the exchange of DHR information through CDLIS. CDLIS costs may result, however, if AAMVA determines that software updates are necessary at the State level to accomplish this change. At this time, the existence or extent of potential CDLIS update costs is unknown. If such costs are incurred, States are eligible to apply for Commercial Driver License Program Implementation grants.

Further, FMCSA is aware that at least one State believes exclusively electronic exchange of DHR information would result in a cost savings. Some States currently employ people and/or pay overtime to process paper convictions; the more efficient electronic submission of DHR information will allow those resources to be used for other purposes. FMCSA does not know the extent of these cost savings in any given State, or the number of States that would experience a cost savings.

B. Congressional Review Act

This rule is not a major rule as defined under the Congressional Review Act (5 U.S.C. 801, *et seq.*).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601, *et seq.*) applies to any rule subject to notice and comment rulemaking under section 553(b) of the APA and requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. FMCSA is not required to complete a regulatory flexibility analysis, because, as discussed earlier in the Legal Basis section, this action is not subject to notice and comment under section 553(b) of the APA.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996,[2] FMCSA wants to assist small entities in understanding this final rule so they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the final rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance; please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $168 million (which is the value equivalent of $100,000,000 in 1995, adjusted for inflation to 2019 levels) or more in any one year. Though this final rule will not result in such an expenditure, the Agency does discuss the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act

This final rule contains no new information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

[2] Public Law 104–121, 110 Stat. 857, (Mar. 29, 1996).

G. E.O. 13132 (Federalism)

A rule has implications for federalism under Section 1(a) of Executive Order 13132 if it has ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This rule amends the CDL regulations in 49 CFR part 384 to align regulatory requirements with existing statutory requirements on States. Because this rule makes conforming, and not substantive, changes to requirements already imposed on States in the CDL program, FMCSA has determined that it does not have substantial direct effects on the States, on the relationship between the Federal and State governments, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Privacy Impact Assessment

The Consolidated Appropriations Act, 2005, (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. Because this rule does not require the collection of personally identifiable information, the Agency is not required to conduct a PIA.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program.

The E-Government Act of 2002, Public Law 107–347, section 208, 116 Stat. 2899, 2921 (Dec. 17, 2002), requires Federal agencies to conduct PIA for new or substantially changed technology that collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information as a result of this rule. As a result, FMCSA has not conducted a PIA.

I. E.O. 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

J. National Environment Policy Act of 1969

FMCSA analyzed this rule pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, Mar. 1, 2004), Appendix 2, paragraphs (6)(t)(1). The Categorical Exclusion (CE) in paragraph (6)(t)(1) covers requirements for regulations to ensure that the States comply with the provisions of the Commercial Motor Vehicle Safety Act of 1986, by including the minimum standards for the actions States must take to be in substantial compliance with each of the statutory requirements of 49 U.S.C. 31311(a). The content in this rule is covered by this CE and the final action does not have any effect on the quality of the environment.

List of Subjects in 49 CFR Part 384

Administrative practice and procedure, Alcohol abuse, Drug abuse, Highway safety, and Motor carriers.

Accordingly, FMCSA amends 49 CFR part 384 as follows:

PART 384—STATE COMPLIANCE WITH COMMERCIAL DRIVER'S LICENSE PROGRAM

■ 1. The authority citation for part 384 is revised to read as follows:

Authority: 49 U.S.C. 31136, 31301 *et seq.,* 31502; secs. 103 and 215, Pub. L. 106–159, 113 Stat. 1753, 1767; sec. 32934, Pub. L. 112–141, 126 Stat. 405, 830; and 49 CFR 1.87.

■ 2. Amend § 384.208 by revising paragraph (a) to read as follows:

§ 384.208 Notification of disqualification.

(a) No later than 10 days after disqualifying a CLP or CDL holder licensed by another State, or disqualifying an out-of-State CLP or CDL holder's privilege to operate a commercial motor vehicle for at least 60 days, the State must notify the State that issued the license of the disqualification via CDLIS.

* * * * *

■ 3. Amend § 384.209 by revising paragraph (c) to read as follows:

§ 384.209 Notification of traffic violations.

* * * * *

(c) *Required timing of notification.* Notification of traffic violations must be made within 10 days of the conviction and must be transmitted through CDLIS.

■ 4. Amend § 384.301 by adding paragraph (n) to read as follows:

§ 384.301 Substantial compliance-general requirements.

* * * * *

(n) A State must come into substantial compliance with the requirements of this part in effect as of August 23, 2021, as soon as practicable, but not later than August 22, 2024.

Issued under authority delegated in 49 CFR 1.87.

Meera Joshi,

Deputy Administrator.

[FR Doc. 2021–15693 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–EX–P

Proposed Rules

Federal Register
Vol. 86, No. 139
Friday, July 23, 2021

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0577; Project Identifier AD–2021–00470–E]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2021–05–16, which applies to certain Pratt & Whitney Division (PW) PW4164, PW4164–1D, PW4168, PW4168–1D, PW4168A, PW4168A–1D, and PW4170 model turbofan engines. AD 2021–05–16 requires initial and repetitive replacements of the low-pressure turbine (LPT) 4th-stage air sealing ring segment assemblies with parts eligible for installation. AD 2021–05–16 also requires initial and repetitive dimensional inspections of the LPT case for bulging and, depending on the results of the dimensional inspections, repair or replacement of the LPT case. Since the FAA issued AD 2021–05–16, the FAA was notified of an inadvertent omission in the LPT 4th-stage air sealing ring segment assembly part numbers. This proposed AD would correct this omission. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 7, 2021.

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

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

For service information identified in this NPRM, contact Pratt & Whitney, 400 Main Street, East Hartford, CT 06118; phone: (800) 565–0140; email: *help24@prattwhitney.com;* website: *https://prattwhitney.com.* You may view this service information at the Airworthiness Products Section, Operational Safety Branch, FAA, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0577; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Carol Nguyen, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7655; fax: (781) 238–7199; email: *carol.nguyen@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0577; Project Identifier AD–2021–00470–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Carol Nguyen, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2021–05–16, Amendment 39–21459 (86 FR 17287, April 2, 2021), (AD 2021–05–16), for certain PW PW4164, PW4164–1D, PW4168, PW4168–1D, PW4168A, PW4168A–1D, and PW4170 model turbofan engines with LPT 4th-stage air sealing ring segment assemblies, part number (P/N) 50N463–01 or P/N 50N526–01, installed. AD 2021–05–16 was prompted by six reports from the manufacturer concerning LPT 4th-stage vane cluster assemblies leaning back and notching into rotating LPT 4th-stage blades, causing some blades to fracture and release. These incidents resulted in an aborted takeoff, air turnbacks, engine surges, high vibrations, and unplanned engine removals. The incidents were attributed to the LPT 4th-stage air sealing ring segment assemblies moving into the LPT 4th-stage blades knife edge seals, resulting in damage to the ring

segment assemblies. AD 2021–05–16 requires initial and repetitive replacements of the LPT 4th-stage air sealing ring segment assemblies with parts eligible for installation. AD 2021–05–16 also requires initial and repetitive dimensional inspections of the LPT case for bulging and, depending on the results of the dimensional inspections, repair or replacement of the LPT case. The agency issued AD 2021–05–16 to prevent damage to the LPT 4th-stage air sealing ring segment assemblies, the LPT case, and the LPT 4th-stage blades. The unsafe condition, if not addressed, could result in uncontained release of the LPT 4th-stage blades, damage to the engine, and damage to the airplane.

Actions Since AD 2021–05–16 Was Issued

Since the FAA issued AD 2021–05–16, the FAA was notified by a manufacturer of parts manufacturer approval (PMA) parts and that paragraphs (c), (g), and (h) of the AD should include affected PMA part numbers because the unsafe condition also applies to those parts. The FAA added FAA-approved equivalent part numbers to paragraphs (c), (g), and (h) of this AD to include PMA part numbers.

FAA's Determination

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

Related Service Information Under 1 CFR Part 51

The FAA reviewed Pratt & Whitney Alert Service Bulletin No. PW4G–100–A72–262, Revision No. 1, dated September 3, 2020 (the ASB). The ASB specifies procedures for replacing the LPT 4th-stage air sealing ring segment assemblies and inspecting the LPT case for bulging. The Director of the Federal Register approved the ASB for incorporation by reference as of May 7, 2021 (86 FR 17287, April 2, 2021). This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Proposed AD Requirements in This NPRM

This proposed AD would retain all the requirements of AD 2021–05–16. This proposed AD would add ''or FAA-approved equivalent part numbers'' to paragraph (c), Applicability; paragraph (g), Required Actions; and paragraph (h), Definitions, of this AD. This proposed AD would also add paragraph (i), Credit for Previous Actions, allowing operators to take credit for the required actions in paragraph (g)(4) of this AD if, prior to the effective date of this AD, operators performed dimensional inspections of the LPT case for bulging using Pratt & Whitney ASB No. PW4G–100–A72–262, Original Issue, dated October 22, 2019.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 99 engines installed on airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect the LPT case for bulging	2 work-hours × $85 per hour = $170	$0	$170	$16,830
Replace the LPT 4th-stage air sealing ring segment assemblies.	50 work-hours × $85 per hour = $4,250	64,592	68,842	6,815,358

The FAA estimates the following costs to do any necessary repair or replacement that would be required based on the results of the proposed inspection. The agency has no way of determining the number of aircraft that might need these repairs or replacements.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Repair LPT case to restore dimensions	250 work-hours × $85 per hour = $21,250	$0	$21,250
Replace the LPT case	0 work-hours × $85 per hour = $0	1,300,000	1,300,000

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive AD 2021–05–16, Amendment 39–21459 (86 FR 17287, April 2, 2021); and

■ b. Adding the following new airworthiness directive:

Pratt & Whitney Division: Docket No. FAA–2021–0577; Project Identifier AD–2021–00470–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) action by September 7, 2021.

(b) Affected ADs

This AD replaces AD 2021–05–16, Amendment 39–21459 (86 FR 17287, April 2, 2021).

(c) Applicability

This AD applies to Pratt & Whitney Division (PW) PW4164, PW4164–1D, PW4168, PW4168–1D, PW4168A, PW4168A–1D, and PW4170 model turbofan engines with low-pressure turbine (LPT) 4th-stage air sealing ring segment assemblies, part number (P/N) 50N463–01, P/N 50N526–01, or FAA-approved equivalent part numbers, installed.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by several reports from the manufacturer concerning LPT 4th-stage vane cluster assemblies leaning back and notching into the rotating LPT 4th-stage blades, causing some blades to fracture and release. A manufacturer investigation into those reports determined that the leaning back of the LPT 4th-stage vane cluster assemblies was caused by damage to the LPT 4th-stage air sealing ring segment assemblies. The FAA is issuing this AD to prevent damage to the LPT 4th-stage air sealing ring segment assemblies, the LPT case, and the LPT 4th-stage blades. The unsafe condition, if not addressed, could result in uncontained release of the LPT 4th-stage blades, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

(1) For affected engines that have either the Talon IIA outer combustion chamber assembly, P/N 51J100 or P/N 51J382, or the Talon IIB outer combustion chamber assembly, P/N 51J381 or P/N 51J500, installed, at the next engine shop visit after the effective date of this AD, remove from service the LPT 4th-stage air sealing ring segment assemblies, P/N 50N463–01, P/N 50N526–01, or FAA-approved equivalent part numbers, and replace with parts eligible for installation.

(2) For affected engines not referenced in paragraph (g)(1) of this AD, at the next LPT overhaul after the effective date of this AD, remove from service the LPT 4th-stage air sealing ring segment assemblies, P/N 50N463–01, P/N 50N526–01, or FAA-approved equivalent part numbers, and replace with parts eligible for installation.

(3) For all affected engines, at each LPT overhaul after compliance with the required actions in paragraphs (g)(1) or (2) of this AD, remove from service the LPT 4th-stage air sealing ring segment assemblies, P/N 50N526–01 or FAA-approved equivalent part numbers, and replace with parts eligible for installation.

(4) During each replacement of the LPT 4th-stage air sealing ring segment assemblies required by paragraphs (g)(1) through (3) of this AD, perform a dimensional inspection of the LPT case for bulging in accordance with the Accomplishment Instructions, paragraph 2, of PW Alert Service Bulletin No. PW4G–100–A72–262 Revision No. 1, dated September 3, 2020 (the ASB).

(5) If, during the dimensional inspection of the LPT case required by paragraph (g)(4) of this AD, any LPT case found to be outside the serviceable limits specified in Table 1: Serviceable Limits and Repairs of the ASB, repair or replace the LPT case before further flight.

(h) Definitions

For the purpose of this AD:

(1) An ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges H through P. The separation of engine flanges solely for the purpose of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(2) An ''LPT overhaul'' is when the LPT rotor is removed from the engine, all four disks are removed from the LPT rotor, and all blades are removed from the disks.

(3) ''Parts eligible for installation'' are LPT 4th-stage air sealing ring segment assemblies, P/N 50N526–01, or FAA-approved equivalent part numbers, with zero flight cycles since new or with a P/N not mentioned in this AD.

(i) Credit for Previous Actions

You may take credit for the dimensional inspection of the LPT case for bulging required by paragraph (g)(4) of this AD if the inspection was performed before the effective date of this AD using PW ASB No. PW4G–100–A72–262 Original Issue, dated October 22, 2019.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

(1) For more information about this AD, contact Carol Nguyen, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7655; fax: (781) 238–7199; email: *carol.nguyen@faa.gov*.

(2) For service information identified in this AD, contact Pratt & Whitney, 400 Main Street, East Hartford, CT 06118; phone: (800) 565–0140; email: *help24@prattwhitney.com;* website: *https://prattwhitney.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

Issued on July 16, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15518 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0574; Project Identifier 2019–SW–073–AD]

RIN 2120–AA64

Airworthiness Directives; Hélicoptères Guimbal Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Hélicoptères Guimbal Model CABRI G2 helicopters. This proposed AD was prompted by a report that,

during scheduled maintenance on two helicopters, cracks were found on a certain main rotor (MR) non-rotating scissor link. This proposed AD would require replacing an affected MR non-rotating scissor link with a serviceable part. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 23, 2021.

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

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

For service information identified in this NPRM, contact Hélicoptères Guimbal, 1070, rue du Lieutenant Parayre, Aérodrome d'Aix-en-Provence, 13290 Les Milles, France; telephone 33–04–42–39–10–88; email *support@guimbal.com;* or at *https://www.guimbal.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. Service information that is incorporated by reference is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0574.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0574; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the European Union Aviation Safety Agency (EASA) AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0574; Project Identifier 2019–SW–073–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0186, dated July 30, 2019 (EASA AD 2019–0186), to correct an unsafe condition for Hélicoptères Guimbal Model CABRI G2 helicopters, all manufacturer serial numbers. EASA advises that, during scheduled maintenance on two helicopters, cracks were found on the MR non-rotating scissor link, part number (P/N) G41–10–200. The suspected root cause for the cracking is corrosion due to stress induced by the mounting of the metal bushings inside the lug hole. To address this issue the manufacturer modified the design of the MR non-rotating scissor link to reinforce the lugs and replace the metal bushings with plastic bushings. Cracking of a MR non-rotating scissor link, if not addressed, could result in failure of that scissor link, resulting in reduced control of the helicopter.

Accordingly, EASA AD 2019–0186 requires replacement of affected MR non-rotating scissor links with serviceable parts.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Guimbal Service Bulletin SB 15–015, Revision C, dated August 27, 2019. This service information specifies procedures for, among other actions, modifying the helicopter by replacing the MR non-rotating scissor link, P/N G41–10–200, with a serviceable part, P/N G41–10–201 (by installing scissor link assembly, P/N G41–12–100, which includes MR non-rotating scissor link, P/N G41–10–201) and torqueing the bolts. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

The FAA also reviewed Guimbal Service Bulletin SB 15–015, Revision A, dated July 20, 2015 (SB 15–015, Revision A); and SB 15–015, Revision B, dated July 12, 2019 (SB 15–015, Revision B). SB 15–015, Revision A, describes procedures for replacing a MR

non-rotating scissor link, P/N G41–10–200, with P/N G41–12–100, which has a new, improved design. Service Bulletin SB 15–015, Revision B, describes the same procedures as SB 15–015, Revision A, and includes a revised compliance time, an updated Situation section, and added an action.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 32 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement	1 work-hour × $85 per hour = $85	$323	$408	$13,056

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Would not affect intrastate aviation in Alaska.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Hélicoptères Guimbal: Docket No. FAA–2021–0574; Project Identifier 2019–SW–073–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 23, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Hélicoptères Guimbal Model CABRI G2 helicopters, certificated in any category, with main rotor (MR) non-rotating scissor links, part number (P/N) G41–10–200 installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft Flight Control.

(e) Unsafe Condition

This AD was prompted by a report that during scheduled maintenance on two helicopters, cracks were found on the MR non-rotating scissor link with part number (P/N) G41–10–200. The FAA is issuing this AD to address cracking of a MR non-rotating scissor link. Cracking of a MR non-rotating scissor link, if not addressed, could result in failure of that scissor link, resulting in reduced control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 50 hours time-in-service or 2 months after the effective date of this AD, whichever occurs first, modify the helicopter by replacing the MR non-rotating scissor link, P/N G41–10–200, with a serviceable scissor link assembly, P/N G41–12–100, in accordance with the Required Actions, IPC 4.1–2 (a) through (d) inclusive, of Guimbal Service Bulletin SB 15–015, Revision C, dated August 27, 2019.

(2) As of the effective date of this AD, do not install a MR non-rotating scissor link, P/N G41–10–200, on any helicopter.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g)(1) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (h)(1) or (2) of this AD.

(1) Guimbal Service Bulletin SB 15–015, Revision A, dated July 20, 2015.

(2) Guimbal Service Bulletin SB 15–015, Revision B, dated July 12, 2019.

(i) Special Flight Permits

Special flight permits, as described in 14 CFR 21.197 and 21.199, are prohibited.

(j) Alternative Methods of Compliance (AMOCs)

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

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

(k) Related Information

(1) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.*

(2) For service information identified in this AD, contact Hélicoptères Guimbal, 1070, rue du Lieutenant Parayre, Aérodrome d'Aix-en-Provence, 13290 Les Milles, France; telephone 33–04–42–39–10–88; email *support@guimbal.com;* or at *https://www.guimbal.com.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in European Union Aviation Safety Agency (EASA) AD 2019–0186, dated July 30, 2019. You may view the EASA AD at *https://www.regulations.gov* in Docket No. FAA–2021–0574.

Issued on July 14, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15475 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0575; Project Identifier MCAI–2020–00545–R]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) (Bell) Model 429 helicopters. This proposed AD was prompted by reports of incorrectly staked spherical bearings in the directional control bellcrank assembly. This proposed AD would require a one-time inspection of the lower surface of the spherical bearing in the directional control bellcrank assembly to determine if it is properly staked and, depending on the findings, applicable corrective actions. For certain helicopters, this proposed AD would also require repetitive inspections and, depending on the findings, applicable corrective actions. This proposed AD would also provide a terminating action for the repetitive inspections. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD September 7, 2021.

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

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

For service information identified in this NPRM, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J 1R4, Canada; telephone 1–450–437–2862 or 1–800–363–8023; fax 1–450–433–0272; email *productsupport@bellflight.com;* or at *https://www.bellflight.com/support/contact-support.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0575; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the Transport Canada AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0575; Project Identifier MCAI–2020–00545–R'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Canadian AD CF–2020–11, dated April 16, 2020 (Transport Canada AD CF–2020–11), to correct an unsafe

condition for Bell Textron Canada Limited (Bell) Model 429 helicopters, serial numbers 57001 through 57210, 57212 through 57344, 57346 through 57371, 57374 through 57377, and 57380. Transport Canada advises that there are reports of incorrectly staked spherical bearings in the directional control bellcrank assembly. This condition, if not addressed, could result in wear or elongation of the bore in the bellcrank, which could result in reduced helicopter directional control.

Accordingly, Transport Canada AD CF–2020–11 requires a one-time inspection to determine if a spherical bearing is properly staked in the directional control bellcrank assembly, and, depending on the findings, replacement of the spherical bearing with a new spherical bearing, repair of an affected bellcrank assembly and repetitive inspections of that repaired bellcrank assembly, or replacement of the affected bellcrank assembly with a serviceable part. Transport Canada AD CF–2020–11 also provides terminating actions for the requirements of the Canadian AD.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with Canada, Transport Canada, its technical representative, has notified the FAA of the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Bell Alert Service Bulletin 429–19–50, Revision B, dated December 19, 2019. This service information specifies procedures for an initial inspection of the lower surface of the spherical bearing in the directional control bellcrank assembly to determine if it is properly staked, additional inspections, and corrective actions. The corrective actions include installation of a new spherical bearing, repair (including re-identification of the bellcrank assembly part number), and replacement of the bellcrank assembly. The additional inspections include an inspection of the upper surface of the spherical bearing in the directional control bellcrank assembly to determine if it is properly staked, an inspection of the bore in the bellcrank assembly for excessive wear (including mechanical or corrosion damage that exceed 0.001 inch (0.03 millimeter) maximum depth for ¼ of the circumference, and any cracking); and, for any helicopter with a bellcrank assembly that is repaired, repetitive inspections of the lower surface of the spherical bearing to determine if it has moved.

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

Other Related Service Information

The FAA also reviewed Bell Alert Service Bulletin 429–19–50, dated November 27, 2019; and Revision A, dated December 2, 2019. Bell Alert Service Bulletin 429–19–50, dated November 27, 2019, specifies procedures for an initial inspection of the spherical bearing in the directional control bellcrank assembly to determine if it is properly staked and replacement of the spherical bearing with a new spherical bearing if it is determined that the spherical bearing was not properly staked.

Bell Alert Service Bulletin 429–19–50, Revision A, dated December 2, 2019, specifies procedures for an initial inspection of the lower surface of the spherical bearing in the directional control bellcrank assembly to determine if it is properly staked, additional inspections, and corrective actions. The corrective actions include installation of a new spherical bearing. The additional inspections include an inspection of the upper surface of the spherical bearing in the directional control bellcrank assembly to determine if it is properly staked, and an inspection of the bore in the bellcrank assembly for excessive wear.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the service information already described.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 120 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	1 work-hour × $85 per hour = $85 per inspection cycle	$0	$85	$10,200

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement Spherical Bearing	7 work-hours × $85 per hour = $595	$56	$651.
Repair/replacement Bellcrank	4 work-hours × $85 per hour = $340	2,856	3,196.
Repetitive Inspections	1 work-hour × $85 per hour = $85 per inspection cycle.	0	85 per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bell Textron Canada Limited (Type Certificate Previously Held by Bell Helicopter Textron Canada Limited): Docket No. FAA–2021–0575; Project Identifier MCAI–2020–00545–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 7, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bell Textron Canada Limited (type certificate previously held by Bell Helicopter Textron Canada Limited) Model 429 helicopters, certificated in any category, serial numbers 57001 through 57210 inclusive, 57212 through 57344 inclusive, 57346 through 57371 inclusive, 57374 through 57377 inclusive, and 57380.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6700, Rotorcraft Flight Control.

(e) Unsafe Condition

This AD was prompted by reports of incorrectly staked spherical bearings in the directional control bellcrank assembly. The FAA is issuing this AD to address incorrectly staked spherical bearings in the directional control bellcrank assembly. This condition, if not addressed, could result in wear or elongation of the bore in the bellcrank, which could result in reduced helicopter directional control.

(f) Compliance

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

(g) Required Inspection and Corrective Actions

Within 25 hours time-in-service (TIS) or 90 days, whichever occurs first after the effective date of this AD: Inspect the lower surface of the spherical bearing on the directional control bellcrank assembly to determine if it is properly staked, in accordance with the Accomplishment Instructions, Part I, step 7., of Bell Alert Service Bulletin 429–19–50, Revision B, dated December 19, 2019 (BASB 429–19–50, Revision B). After the inspection, before further flight, do the applicable action required by paragraph (g)(1) or (2) of this AD.

(1) If the lower surface of the spherical bearing is improperly staked (any discrepancy is found *e.g.,* the witness marks are not present and intact or the staked lip is not uniform along the chamfer): Inspect the bore in the bellcrank assembly for excessive wear (including mechanical or corrosion damage that exceed 0.001 inch (0.03 millimeter) maximum depth for ¼ of the circumference, and any cracking); in accordance with the Accomplishment Instructions, Part I, steps 10. through 13., of BASB 429–19–50, Revision B, and depending on the findings, do the applicable actions required by paragraph (g)(1)(i) or (ii) of this AD before further flight.

(i) If the bore in the bellcrank assembly shows signs of excessive wear: Repair the bellcrank, including re-identifying the bellcrank assembly part number, in accordance with the Accomplishment Instructions, Part II, steps 1. through 13., of BASB 429–19–50, Revision B.

(ii) If the bore diameter is within 0.001 inch (0.03 millimeter) maximum depth for ¼ of the circumference: Install a new spherical bearing, in accordance with the Accomplishment Instructions, Part II, steps 4. through 12., of BASB 429–19–50, Revision B.

(2) If the lower surface of the spherical bearing is properly staked: Inspect the upper surface of the spherical bearing on the directional control bellcrank assembly to determine if it is properly staked, in accordance with the Accomplishment Instructions, Part I, steps 8. and 9., of BASB 429–19–50, Revision B, and depending on the findings, do the applicable actions required by paragraph (g)(2)(i) or (ii) of this AD before further flight.

(i) If the spherical bearing is properly staked: No further action is required by this AD.

(ii) If the spherical bearing is not properly staked (any discrepancy is found *e.g.,* the witness marks are not present and intact or the staked lip is not uniform along the chamfer): Inspect the bore in the bellcrank assembly for excessive wear (including mechanical or corrosion damage that exceed 0.001 inch (0.03 millimeter) maximum depth for ¼ of the circumference, and any cracking), in accordance with the Accomplishment Instructions, Part I, steps 10. through 13., of BASB 429–19–50, Revision B, and depending on the findings, do the applicable actions required by paragraph (g)(2)(ii)(A) or (B) of this AD before further flight.

(A) If the bore in the bellcrank assembly shows signs of excessive wear: Repair the bellcrank, including re-identifying the bellcrank assembly part number, in accordance with the Accomplishment Instruction, Part II, steps 1. through 13., of BASB 429–19–50, Revision B.

(B) If the bore diameter is within 0.001 inch (0.03 millimeter) maximum depth for ¼ of the circumference: Install a new spherical bearing, in accordance with the Accomplishment Instructions, Part II, steps 4. through 12., of BASB 429–19–50, Revision B.

(h) Required Post Repair Inspections

For any helicopter on which the bellcrank has been repaired as required by paragraphs (g)(1)(i) or (g)(2)(ii)(A) of this AD: Within 100 hours TIS after the repair, and thereafter at intervals not to exceed 100 hours TIS, inspect the lower surface of the spherical bearing to determine if it has moved, in accordance with the Accomplishment Instructions, Part III, step 7., of BASB 429–19–50, Revision B. If the spherical bearing has moved (is loose): Before further flight, inspect the bore in the bellcrank assembly to determine if the diameter exceeds 0.6283 inch (15.9588 millimeters), in accordance with the Accomplishment Instructions, Part III, steps 8. through 11., of BASB 429–19–50, Revision B.

(1) If the diameter of the bore in the bellcrank assembly exceeds 0.6283 inch (15.9588 millimeters): Before further flight replace the bellcrank assembly.

(2) If the diameter of the bore in the bellcrank assembly does not exceed 0.6283 inch (15.9588 millimeters): Before further flight install a new spherical bearing in

accordance with the Accomplishment Instructions, Part II, steps 4. through 12., of BASB 429–19–50, Revision B.

(i) Terminating Action

Replacement of a bellcrank assembly with a new part (never installed on a helicopter or has accumulated zero hours TIS) is terminating action for the requirements of this AD for that helicopter only.

(j) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the service information identified in paragraph (j)(1) or (2) of this AD.

(1) Bell Alert Service Bulletin 429–19–50, dated November 27, 2019.

(2) Bell Alert Service Bulletin 429–19–50, Revision A, dated December 2, 2019.

(k) Alternative Methods of Compliance (AMOCs)

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

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

(l) Related Information

(1) For more information about this AD, contact Andrea Jimenez, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7330; email *andrea.jimenez@faa.gov.*

(2) For service information identified in this AD, contact Bell Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J 1R4, Canada; telephone 1–450–437–2862 or 1–800–363–8023; fax 1–450–433–0272; email *productsupport@bellflight.com;* or at *https://www.bellflight.com/support/contact-support.* You may view this referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(3) The subject of this AD is addressed in Transport Canada AD CF–2020–11, dated April 16, 2020. You may view the Transport Canada AD on the internet at *https://www.regulations.gov* in Docket No. FAA–2021–0575.

Issued on July 15, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15534 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0713; Product Identifier 2019–CE–061–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA is withdrawing a notice of proposed rulemaking (NPRM) that proposed to adopt a new airworthiness directive (AD) for certain Gulfstream Aerospace Corporation (Gulfstream) Model GVII–G500 airplanes. The NPRM was prompted by a report of a fuel quantity disparity between the overhead panel touch screens and the touch screen controllers. The NPRM proposed to require incorporating operating limitations into the airplane flight manual (AFM) until the fuel quantity management system (FQMS) software is updated. Since issuance of the NPRM, the FAA has determined that there is not an unsafe condition because all affected airplanes have updated software. Accordingly, the NPRM is withdrawn.

DATES: As of July 23, 2021, the proposed rule, which published in the **Federal Register** on July 28, 2020 (85 FR 45345), is withdrawn.

ADDRESSES:

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0713; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD action, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jared Meyer, Aviation Safety Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, GA 30337; phone: (404) 474–5534; fax: (404) 474–5605; email: *jared.meyer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued an NPRM that proposed to amend 14 CFR part 39 by adding an AD that would apply to certain serial-numbered Gulfstream Model GVII–G500 airplanes. The NPRM published in the **Federal Register** on July 28, 2020 (85 FR 45345). The NPRM was prompted by a report of the affected airplanes exhibiting a disparity between the fuel quantities displayed on the overhead panel touch screens and the fuel quantities displayed on the touch screen controllers. An investigation revealed two known failure conditions that the Model GVII–G500 FQMS does not properly detect and report to the crew. These failure conditions are fuel quantity probe drift and an FQMS over-current condition, which could result in erroneous and misleading fuel quantity indications and could also result in erroneous and misleading fuel imbalance indications. These conditions could cause a false annunciation of a fuel imbalance, a failure to annunciate an actual fuel imbalance, and a condition where the actual fuel quantity is less than or greater than the indicated fuel quantity. The FQMS software logic does not properly detect or compensate for these failure conditions. This condition, if not corrected, could result in fuel starvation during flight, performance impacts of the airplane having more fuel than indicated, and a roll moment due to a fuel imbalance.

The NPRM proposed to require incorporating operating limitations into the AFM until the fuel quantity signal conditioner FQMS software is updated to version 10003–42130–01–19.03.

Actions Since the NPRM Was Issued

After issuance of the NPRM, the FAA determined that all Gulfstream Model GVII–G500 airplanes are in compliance with the proposed software update, and the unsafe condition has been removed from the fleet. In addition, since Gulfstream controls the software, it is unlikely the unsafe condition will be re-introduced.

Based on the above information, the FAA has determined that AD action is not warranted and the proposal should be withdrawn.

Comments

The FAA received comments from Gulfstream and an individual commenter.

Requests

Gulfstream requested that the FAA change the credit for previous actions. The individual commenter requested the FAA clarify the correct revision of the service information to reference.

The FAA acknowledges these comments. However, because the NPRM is being withdrawn, the commenters' requests are no longer necessary.

Withdrawal of the NPRM constitutes only such action and does not preclude the FAA from further rulemaking on this issue, nor does it commit the FAA to any course of action in the future.

Regulatory Findings

Since this action only withdraws an NPRM, it is neither a proposed AD nor a final rule. This action, therefore, is not covered under Executive Order 12866 or the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Withdrawal

■ Accordingly, the notice of proposed rulemaking, which published in the **Federal Register** on July 28, 2020 (85 FR 45345), is withdrawn.

Issued on July 15, 2021.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15533 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0578; Project Identifier 2018–SW–084–AD]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Leonardo S.p.a Model AW169 helicopters. This proposed AD was prompted by reports of in-flight pilot collective stick oscillation. This proposed AD would require a one-time measurement of the friction of the pilot collective stick assembly to verify that it is within the allowable range and, depending on findings, making an adjustment to restore the acceptable level of friction, as specified in a European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by September 7, 2021.

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

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

For EASA material that is proposed for IBR in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view the EASA material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of the EASA material at the FAA, call (817) 222–5110. The EASA material is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0578.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0578; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the EASA AD, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0578; Project Identifier 2018–SW–084–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will

be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0203, dated September 12, 2018 (EASA AD 2018–0203), to correct an unsafe condition for Leonardo S.p.A., formerly Finmeccanica S.p.A. and AgustaWestland S.p.A., Model AW169 helicopters, all serial numbers equipped with pilot collective stick assemblies having part number (P/N) 6F6711A07832 or P/N 6F6711A07831.

This proposed AD was prompted by reports of in-flight pilot collective stick oscillation. Based on the investigation results, it was determined that this was likely due to an incorrect adjustment on the collective stick fixed friction during helicopter assembly, or during a maintenance action. Incorrect adjustment of the collective friction of the flight control system could lead to a reduction in the safety margins of controllability of an affected helicopter. To address this issue, EASA issued AD 2017–0137, dated August 1, 2017, to require a one-time measurement of the collective stick fixed friction value. After that EASA AD was issued an additional event was reported involving a helicopter that was not affected by EASA AD 2017–0137. EASA AD 2018–0203 supersedes EASA AD 2017–0137. The FAA is proposing this AD to address incorrect adjustment of the pilot collective stick fixed friction. The unsafe condition, if not addressed, could result in reduced controllability of the helicopter, and subsequent damage to the helicopter and injury to occupants. See EASA AD 2018–0203 for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2018–0203 requires a one-time measurement of the friction of the pilot collective stick assembly to verify that it is within the allowable range specified in the service information (collective up and collective down directions 9.00/18.00N (Newton) or 2.02/4.05 lbf (pound force)) and, depending on the findings, accomplishment of the corrective action. The corrective action is making an adjustment to the pilot collective stick assembly to restore the acceptable level of friction. EASA AD 2018–0203 also specifies that after installation of an affected part, or following maintenance of an affected part that involves removal from the helicopter and re-installation, before the next flight after the part installation, the collective fixed friction must be measured and, depending on the findings, the corrective action must be accomplished.

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

FAA's Determination and Requirements of This Proposed AD

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA about the unsafe condition described in its AD. The FAA is proposing this AD after evaluating all known relevant information and determining that the unsafe condition described previously is likely to exist or develop on other helicopters of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2018–0203, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use certain civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, EASA AD 2018–0203 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2018–0203 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2018–0203 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2018–0203. Service information specified in EASA AD 2018–0203 that is required for compliance with it will be available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0578 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 6 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Functional check—friction measurement	2 work-hours × $85 per hour = $170	$0	$170	$1,020

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

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Adjustment	2 work-hours × $85 per hour = $170	$0	$170

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Leonardo S.p.a.: Docket No. FAA–2021–0578; Project Identifier 2018–SW–084–AD.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 7, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Leonardo S.p.a. Model AW169 helicopters, certificated in any category, with an affected part as identified in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0203, dated September 12, 2018 (EASA AD 2018–0203) installed.

(d) Subject

Joint Aircraft Service Component (JASC) Codes: 6700, Rotorcraft Flight Control; 6710, Main Rotor Control.

(e) Unsafe Condition

This AD was prompted by reports of in-flight pilot collective stick oscillation. The FAA is issuing this AD address incorrect adjustment of the pilot collective stick fixed friction. The unsafe condition, if not addressed, could result in reduced controllability of the helicopter, and subsequent damage to the helicopter and injury to occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2018–0203.

(h) Exceptions to EASA AD 2018–0203

(1) Where EASA AD 2018–0203 refers to flight hours (FH), this AD requires using hours time-in-service.

(2) Where EASA AD 2018–0203 refers to its effective date, this AD requires using the effective date of this AD.

(3) The ''Remarks'' section of EASA AD 2018–0203 does not apply to this AD.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2018–0203 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

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

(k) Related Information

(1) For EASA AD 2018–0203, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. This material may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0578.

(2) For more information about this AD, contact Darren Gassetto, Aerospace Engineer, COS Program Management Section, Operational Safety Branch, Compliance & Airworthiness Division, FAA, 1600 Stewart Ave., Suite 410, Westbury, NY 11590; telephone (516) 228–7323; email *Darren.Gassetto@faa.gov.*

Issued on July 16, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15555 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0554; Airspace Docket No. 21–AGL–26]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Galesburg, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Galesburg Municipal Airport, Galesburg, IL. The FAA is proposing this action as the result of airspace reviews caused by the decommissioning of the Galesburg very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Comments must be received on or before September 7, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–0554/Airspace Docket No. 21–AGL–26 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E surface area and Class E airspace extending upward from 700 feet above the surface at Galesburg Municipal Airport, Galesburg, IL, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0554/Airspace Docket No. 21–AGL–26.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR 71 by:

Amending the Class E surface area at Galesburg Municipal Airport, Galesburg, IL, by removing the Galesburg VOR/DME and associated extensions from the airspace legal description; and updating the outdated term ''Airport/Facility Directory'' with ''Chart Supplement'';

And amending the Class E airspace extending upward from 700 feet above the surface to within a 6.5-mile (decreased from a 7-mile) radius of Galesburg Municipal Airport.

This action is due to an airspace review caused by the decommissioning of the Galesburg VOR, which provided navigation information for the instrument procedures this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6002 and 6005, respectively, of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations

listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

AGL IL E2 Galesburg, IL [Amended]

Galesburg Municipal Airport, IL
(Lat. 40°56′17″ N, long. 90°25′52″ W)

Within a 4-mile radius of the Galesburg Municipal Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

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

* * * * *

AGL IL E5 Galesburg, IL [Amended]

Galesburg Municipal Airport, IL
(Lat. 40°56′17″ N, long. 90°25′52″ W)
Monmouth Municipal Airport, IL
(Lat. 40°55′47″ N, long. 90°37′52″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Galesburg Municipal Airport, and within a 6.8-mile radius of the Monmouth Municipal Airport.

Issued in Fort Worth, Texas, on July 19, 2021.

Martin A. Skinner,

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

[FR Doc. 2021–15582 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0555; Airspace Docket No. 21–ACE–16]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Salem, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace extending upward from 700 feet above the surface at Salem Memorial Airport, Salem, MO. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Maples very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program.

DATES: Comments must be received on or before September 7, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2021–0555/Airspace Docket No. 21–ACE–16 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the Class E airspace extending upward from 700 feet above the surface at Salem Memorial Airport, Salem, MO, to support instrument flight rule operations at this airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking

by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2021–0555/Airspace Docket No. 21–ACE–16.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at https://www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the at Salem Memorial Airport, Salem, MO, by removing the Maples VORTAC and associated extension from the airspace legal description.

This action is necessary due to an airspace review caused by the decommissioning of the Maples VOR, which provided navigation information for the instrument procedures this airport, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

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

* * * * *

ACE MO E5 Salem, MO [Amended]

Salem Memorial Airport, MO
(Lat. 37°36′55″ N, long. 91°36′16″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Salem Memorial Airport.

Issued in Fort Worth, Texas, on July 19, 2021.

Martin A. Skinner,

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

[FR Doc. 2021–15580 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 005–2020]

Privacy Act of 1974; Implementation

AGENCY: Office of Legal Policy, United States Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: On July 14, 2021, the Office of Legal Policy (OLP), a component within the United States Department of Justice (DOJ or Department), published in the **Federal Register** a notice of a modified system of records for the OLP system of records, Judicial Nominations Files, JUSTICE/OLP–002. In this notice of proposed rulemaking, OLP proposes to modify the exemptions from certain

provisions of the Privacy Act claimed for this system of records, as well as other administrative modifications. For the reasons provided below, the Department proposes to amend its Privacy Act regulations. Public comments are invited.

DATES: Comments must be received by August 23, 2021.

ADDRESSES: You may send comments by any of the following methods:

- *Email: privacy.compliance@usdoj.gov.* To ensure proper handling, please reference the CPCLO Order No. in the subject line of the message.
- *Fax:* 202–307–0693.
- *Mail:* United States Department of Justice, Office of Privacy and Civil Liberties, ATTN: Privacy Analyst, Two Constitution Square (2Con), 145 N Street NE, Suite 8W.300, Washington, DC 20530. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes. To ensure proper handling, please reference the CPCLO Order No. in your correspondence.
- *Federal eRulemaking Portal: http://www.regulations.gov.* When submitting comments electronically, you must include the CPCLO Order No. in the subject box. Please note that the Department is requesting that electronic comments be submitted before midnight Eastern Daylight Savings Time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at that time. Commenters in time zones other than Eastern Time may want to consider this to ensure that their electronic comments are received.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Department's public docket. Such information includes personally identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. If you want to submit personally identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONALLY IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all personally identifying information that you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personally identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, may be posted online and placed in the Department's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph, below.

FOR FURTHER INFORMATION CONTACT: Matrina Matthews, Executive Officer, Office of Legal Policy, U.S. Department of Justice, 950 Pennsylvania Avenue NW, Room 4234, Washington, DC 20530–0001; telephone: (202) 616–0040; email: *matrina.matthews@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The Assistant Attorney General, OLP, is responsible for assisting the Attorney General in, *inter alia,* advising and assisting in the selection and appointment of Federal judges. OLP is comprised of attorneys and other DOJ personnel responsible for assisting the Assistant Attorney General in executing the responsibilities of the office. DOJ established the recently renamed system of records, ''Judicial Nominations Files,'' JUSTICE/OLP–002, to maintain records primarily needed to assist the Assistant Attorney General, OLP, and the personnel within OLP, in assessing candidates for potential nomination to be a Federal judge and securing a judicial nominee's confirmation and appointment.

OLP updated the system of records notice for JUSTICE/OLP–002, 86 FR 37192 (July 14, 2021), to account for a number of organizational, procedural, and technological changes that have modernized the information and information system used to collect, maintain, and disseminate these records. The Department determined that these updates to the system of records notice were necessary to accurately describe the Department's organizational, procedural, and technological changes.

As part of the existing process for reviewing an individual's potential nomination to a Federal judgeship or other related Executive Branch position, and securing confirmation, individuals agree to a number of evaluations, including but not limited to, a full background investigation. As disclosed in JUSTICE/OLP–002, OLP will maintain records relating to these investigations in its system of records. Given the law enforcement and national security information maintained in these records, as well as the examination materials used to assess a potential nominee, the Department has determined that it is appropriate to claim additional exemptions from certain Privacy Act provisions for these records.

Specifically, certain classified information may be maintained in JUSTICE/OLP–002, including but not limited to, records related to a potential nominee that maintained a previous or current position with access to classified information and/or assigned to a national security sensitive position. Given the law enforcement information that may be discovered as part of the nomination investigation and/or evaluations, certain investigatory materials for law enforcement purposes may be maintained in this system of records. Investigatory material may also be used in determining suitability, eligibility, or qualification decisions, and such information may require exemption to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Department under an express promise that the identity of the source would be held in confidence. The Department also utilizes various examination materials to determine individual qualifications for appointment, which if disclosed, could compromise the objectivity or fairness of the Department's examination and vetting process.

Finally, as an administrative matter, the Department proposes to modify 28 CFR 16.73 as a result of the rescindment of JUSTICE/OLP–001, ''Freedom of Information and Privacy Appeals Index,'' and JUSTICE/OLP–004, ''Declassification Review System.'' *See* 66 FR 29994 (June 6, 2001). Specifically, the administrative edits proposed in this rule would: (1) Remove the current paragraphs (g), and (h); and (2) revise 28 CFR 16.73(a), (b), (c), and (d), to account for OLP's two remaining systems of records that claim Privacy Act exemptions—JUSTICE/OLP–002 and the

''General Files System of the Office of Legal Policy,'' JUSTICE/OLP–003.

Executive Orders 12866 and 13563–Regulatory Review

In accordance with 5 U.S.C. 552a(j) and 552a(k), this proposed action is subject to formal rulemaking procedures by giving interested persons an opportunity to participate in the rulemaking process ''through submission of written data, views, or arguments,'' pursuant to 5 U.S.C. 553. The Department has determined that this proposed rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this proposed rule has not been reviewed by the Office of Information and Regulatory Affairs within the Office of Management and Budget pursuant to Executive Order 12866.

Regulatory Flexibility Act

This proposed rule will only impact Privacy Act-protected records, which are personal and generally do not apply to an individual's entrepreneurial capacity, subject to limited exceptions. Accordingly, the Chief Privacy and Civil Liberties Officer, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act of 1996 (Subtitle E–Congressional Review Act)

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, 5 U.S.C. 801 *et seq.,* requires the Department to comply with small entity requests for information and advice about compliance with statutes and regulations within the Department's jurisdiction. Any small entity that has a question regarding this document may contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph, above. Persons can obtain further information regarding SBREFA on the Small Business Administration's web page at *https://www.sba.gov/advocacy.* This proposed rule is not a major rule as defined by 5 U.S.C. 804 of the Congressional Review Act.

Executive Order 13132—Federalism

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12988—Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

This proposed rule will have no implications for Indian Tribal governments. More specifically, it does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Therefore, the consultation requirements of Executive Order 13175 do not apply.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000, as adjusted for inflation, or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. 3507(d), requires the Department to consider the impact of paperwork and other information collection burdens imposed on the public. There are no current or new information collection requirements associated with this proposed rule.

List of Subjects in 28 CFR Part 16

Administrative Practices and Procedures, Courts, Freedom of Information, and the Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 2940–2008, the Department of Justice proposes to amend 28 CFR part 16 as follows:

PART 16—PRODUCTION OR DISCLOSURE OF MATERIAL OR INFORMATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

Subpart E—Exemption of Records Systems Under the Privacy Act

■ 2. Revise § 16.73 to read as follows:

§ 16.73 Exemption of Office of Legal Policy Systems.

(a) The Judicial Nominations Files (JUSTICE/OLP–002) system of records is exempt from subsections (c)(3); (d); (e)(1), (e)(4)(G), (H), and (I); and (f) of the Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), (k)(2), (k)(5), and (k)(6). These exemptions apply only to the extent that information in this system of records is subject to an exemption, pursuant to 5 U.S.C. 552a(k). Where compliance would not appear to interfere with or adversely affect OLP's processes, OLP may waive the applicable exemption.

(b) Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3), the requirement that an accounting be made available to the named subject of a record, because release of disclosure accountings could alert the subject of an investigation and/or evaluation to the extent of an investigation and/or evaluation. Such a disclosure could also reveal investigative interests by not only OLP, but also other recipient agencies or components. Since release of such information to the subjects of an investigation would provide them with significant information concerning the nature of the investigation and/or evaluation, release could result in the destruction of documentary evidence, improper influencing of witnesses, endangerment of the physical safety of confidential sources, witnesses, and law enforcement personnel, the fabrication of testimony, and other activities that could impede or compromise the investigation and/or evaluation. In addition, providing the individual an accounting for each disclosure could result in the release of properly classified information which would compromise the national defense or disrupt foreign policy.

(2) From subsection (d), the access and amendment provisions, because many persons are contacted who, without an assurance of anonymity, refuse to provide information concerning the subject of an

investigation and/or evaluation. Access could reveal the identity of the source of the information and constitute a breach of the promised confidentiality on the part of the Department. Such breaches ultimately would restrict the free flow of information vital to the determination of a candidate's qualifications and suitability, among other determinations. The Department also relies on certain examination materials to assess and evaluate an individual's qualifications for an applicable position. Access and/or amendment to such material could reveal information about the examination and vetting process and could compromise its objectivity and/or fairness. Access and/or amendment to such material could also inappropriately advantage future candidates with knowledge of the examination materials. Finally, providing the individual access or amendment rights could result in the release of properly classified information which would compromise the national defense or disrupt foreign policy.

(3) From subsection (e)(1), because in the collection of information for investigative and evaluative purposes, it is impossible to determine in advance what exact information may be of assistance in determining the qualifications and suitability of the subject of an investigation and/or evaluation. Information which may seem irrelevant, when combined with other seemingly irrelevant information, can on occasion provide a composite picture of a candidate which assists in determining whether that candidate should be nominated for appointment. Relevance and necessity are questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established. In interviewing individuals or obtaining other forms of information during OLP processes, information may be supplied to OLP which relates to matters incidental to the primary purpose of OLP's processes, but also relates to matters under the investigative jurisdiction of another agency. Such information cannot readily be segregated.

(4) From subsections (e)(4)(G) and (H), and subsection (f), because this system is exempt from the access and amendment provisions of subsection (d).

(c) The General Files System of the Office of Legal Policy (JUSTICE/OLP–003) system of records is exempt from subsections 552a(c)(3) and (4); (d); (e)(1), (2) and (3), (e)(4)(G) and (H), and (e)(5); and (g) of the Privacy Act, pursuant to 5 U.S.C. 552a(j)(2), (k)(1), (k)(2) and (k)(5). These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552(j), (k). Where compliance would not appear to interfere with or adversely affect OLP's processes, the applicable exemption may be waived by OLP.

(d) Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) because making available to a record subject the accounting of disclosures from records concerning him/her would reveal investigative interest on the part of the Department as well as the recipient agency. This would permit record subjects to impede the investigation, *e.g.,* destroy evidence, intimidate potential witnesses, or flee the area to avoid inquiries or apprehension by law enforcement personnel.

(2) From subsection (c)(4) because this system is exempt from the access provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

(3) From subsection (d) because the records contained in this system relate to official Federal investigations. Individual access to these records might compromise ongoing investigations, reveal confidential informants, or constitute unwarranted invasions of the personal privacy of third parties who are involved in a certain investigation. Amendment of records would interfere with ongoing criminal law enforcement proceedings and impose an impossible administrative burden by requiring criminal investigations to be continuously reinvestigated.

(4) From subsections (e)(1) and (5) because in the course of law enforcement investigations, information may occasionally be obtained or introduced, the accuracy of which is unclear or which is not strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information since it may aid in establishing patterns of criminal activity. Moreover, it would impede the specific investigation process if it were necessary to assure the relevance, accuracy, timeliness and completeness of all information obtained.

(5) From subsections (e)(2) because in a law enforcement investigation the requirement that information be collected to the greatest extent possible from the subject individual would present a serious impediment to law enforcement in that the subject of the investigation would be informed of the existence of the investigation and would therefore be able to avoid detection, apprehension, or legal obligations and duties.

(6) From subsection (e)(3) because to comply with the requirements of this subsection during the course of an investigation could impede the information gathering process, thus hampering the investigation.

(7) From subsections (e)(4)(G) and (H) because this system is exempt from the access provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

(8) From subsection (g) because this system is exempt from the access and amendment provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

Dated: July 1, 2021.

Peter A. Winn,

Acting Chief Privacy and Civil Liberties Officer, United States Department of Justice.

[FR Doc. 2021–14995 Filed 7–22–21; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AR20

Threshold for Reporting VA Debts to Consumer Reporting Agencies

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations around the conditions by which VA benefits debts or medical debts are reported to consumer reporting agencies (CRA). The Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020 provides the Secretary authority to prescribe regulations that establish the minimum amount of a benefits or medical debt that the Secretary will report to the CRA. This proposed change will establish the methodology for determining a minimum threshold for debts reported to CRA.

DATES: Comments must be received on or before September 21, 2021.

ADDRESSES: Comments may be submitted through *www.regulations.gov* or mailed to Debt Management Center, Office of Management, 189, 1 Federal Drive, Suite 4500, Fort Snelling, MN 55111. Comments should indicate that they are submitted in response to ''RIN 2900–AR20—Threshold for Reporting VA Debts to Consumer Reporting Agencies. Comments received will be

available at *regulations.gov* for public viewing, inspection, or copies.

FOR FURTHER INFORMATION CONTACT: Jason Hoge, Director of Operations, Debt Management Center, Office of Management, 189, 1 Federal Drive, Suite 4500, Fort Snelling, MN 55111, (612) 725–4337. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION:

Summary of Proposed Regulatory Changes

We propose to amend VA's regulation that governs reporting of delinquent debts to CRA. This rulemaking would update the regulation to comply with section 2007 of Public Law 116–315, the Johnny Isakson and David P. Roe, M.D. Veterans Health Care and Benefits Improvement Act of 2020. Section 2007 amends chapter 53 of title 38, United States Code by adding section 5320 as follows: ''The Secretary shall prescribe regulations that establish the minimum amount of a claim or debt, arising from a benefit administered by the Under Secretary for Benefits or Under Secretary for Health, that the Secretary will report to a consumer reporting agency under section 3711 of title 31.''

This proposed amendment will establish the methodology for determining the minimum threshold for reporting certain VA debts to CRA. It will also exclude from the minimum threshold those debts in which there is an indication of fraud, misrepresentation, or bad faith on the part of the debtor.

Background on Governing Statutes

The Debt Collection Improvement Act of 1996 (DCIA), in part, mandated agencies to report delinquent debts to CRA. 31 U.S.C. 3711(e); Sec. 31001(k), Public Law 104–134, 110 Stat. 1321. The purpose of the DCIA includes maximizing collection of delinquent debts by ensuring quick action to recover debts, use of appropriate collection tools, and minimizing the costs of debt collection. Sec. 31001(b), Public Law 104–134.

Section 5320 of title 38, United States Code, authorizes VA to ''establish the minimum amount of a claim or debt, arising from a benefit administered by the Under Secretary for Benefits or Under Secretary for Health, that the Secretary will report to a consumer reporting agency under section 3711 of title 31.'' The intent of section 5320 is to lessen negative impact of CRA reports on Veterans.

Introduction to Proposed Regulatory Changes

As explained in more detail below, we propose to amend 38 CFR 1.916 to comply with 38 U.S.C. 5320, to establish a minimum threshold for reporting debts to CRA.

In accordance with 31 U.S.C. 3711(e), the VA Debt Management Center (DMC) is responsible for reporting delinquent debts to CRA. Prior to January 5, 2021, DMC reported an average of 5,000 delinquent Veteran accounts monthly. DMC regularly receives complaints from Veterans whose accounts have been reported to CRA. Common complaints from Veterans include: Loss of security clearance, inability to obtain approval for home loans or home refinancing, and difficulty securing rental housing.

This proposed amendment recognizes that the debts described in 38 U.S.C. 5320 are fundamentally different from consumer debt. Debts arising from a benefit administered by the Under Secretary for Benefits or the Under Secretary for Health may result from a variety of scenarios, including overpayments that are not the fault of the Veteran.

Section 5320 authorizes the Secretary to establish a minimum threshold that will ultimately reduce the number of debts that will be reported to CRA. This will, in turn, decrease the number of Veterans negatively impacted by these reports. The VA's mission is to ''care for those who shall have borne the battle and for their families and survivors.'' Negative credit reports may cause housing insecurity or job loss, and this result is inconsistent with VA's mission.

38 CFR 1.916— Disclosure of Debt Information to Consumer Reporting Agencies (CRA)

We propose to amend 38 CFR 1.916, which sets forth the requirements for reporting delinquent debts to CRA, by inserting subparagraphs (c)(1) through (3) to provide the methodology used by the Secretary to establish the minimum threshold. This section would also clarify that the minimum threshold applies only to a debt of an individual that arises from a benefit administered by the Under Secretary for Benefits or Under Secretary for Health.

We propose subparagraphs (c)(1) through (3) state:

1. The Secretary has established a minimum threshold for a debt, arising from a benefit administered by the Under Secretary for Benefits or Under Secretary for Health, that the Secretary will report to a consumer reporting agency under section 3711 of title 31.

(2) VA will only report those debts that meet the following standards:

(i) The debt is classified as currently not collectible. For purposes of this paragraph, the debt is currently not collectible if VA has exhausted available collection efforts, including, as appropriate, referrals for administrative offset and enforced collection;

(ii) The debt is not owed by an individual who is determined by VA to be catastrophically disabled or has reported to VA a gross household income below the applicable geographically adjusted income limits that would entitle a VA beneficiary to cost-free health care, medications and/or beneficiary travel; and

(iii) The outstanding debt amount is over $25, or such higher amount VA may from time to time prescribe, in accordance with section 1.921 of this part.

(3) The minimum threshold set forth in this paragraph will not apply if there is an indication of fraud, misrepresentation, or bad faith on the part of the individual in connection with the debt.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). The regulations established by this rulemaking do not impose burdens or otherwise regulate the activities of any small entities outside of VA. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Catalog of Federal Domestic Assistance

There are no Catalog of Federal Domestic Assistance numbers and titles for this rule.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Parking, Penalties, Postal Service, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Wages.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs approved this document on June 23, 2021 and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 1 as set forth below:

PART 1—GENERAL PROVISIONS

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

Authority: 31 U.S.C. 3711(e); 38 U.S.C. 501, 5701(g) and (i); 38 U.S.C. 5320.

§ 1.916 [Amended]

■ 2. Amend § 1.916 by revising paragraph (c) to read as follows:

* * * * *

(c) Subject to the conditions set forth in this paragraph and paragraph (d) of this section, information concerning individuals may be disclosed to consumer reporting agencies for inclusion in consumer reports pertaining to the individual, or for the purpose of locating the individual. Disclosure of the fact of indebtedness will be made if the individual fails to respond in accordance with written demands for repayment, or refuses to repay a debt to the United States. In making any disclosure under this section, VA will provide consumer reporting agencies with sufficient information to identify the individual, including the individual's name, address, if known, date of birth, VA file number, and Social Security number.

(1) The Secretary has established a minimum threshold for a debt, arising from a benefit administered by the Under Secretary for Benefits or Under Secretary for Health, that the Secretary will report to a consumer reporting agency under section 3711 of title 31.

(2) VA will only report those debts that meet the following standards:

(i) The debt is classified as currently not collectible. For purposes of this paragraph, the debt is currently not collectible if VA has exhausted available collection efforts, including, as appropriate, referrals for administrative offset and enforced collection;

(ii) The debt is not owed by an individual who is determined by VA to be catastrophically disabled or has reported to VA a gross household income below the applicable geographically adjusted income limits that would entitle a VA beneficiary to cost-free health care, medications and/or beneficiary travel; and

(iii) The outstanding debt amount is over $25, or such higher amount VA may from time to time prescribe, in accordance with section 1.921 of this part.

(3) The minimum threshold set forth in this paragraph will not apply if there is an indication of fraud, misrepresentation, or bad faith on the part of the individual in connection with the debt.

* * * * *

[FR Doc. 2021–15490 Filed 7–22–21; 8:45 am]

BILLING CODE 8320–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

41 CFR Parts 51–1, 51–2, 51–3, 51–4, 51–5, 51–6, 51–7, 51–8, 51–9, and 51–10

RIN 3037–AA13

Provisions Relating to Public Contracts

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed rule with request for comments.

SUMMARY: This proposed rule would amend the Committee for Purchase From People Who Are Blind or Severely Disabled's (Committee) regulations to address outdated information and proposes correction and clarifications within the chapter or with the Javits-Wagner-O'Day Act or the AbilityOne Program. This regulation was originally published in 1991 and changes in Committee practices and concepts have occurred which requires updates to the CFR. These updates merely are administrative in nature.

DATES: Comments should be submitted on or before August 23, 2021.

ADDRESSES: You may submit your comments, identified by ''RIN 3037–AA13'' by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Comments received will be posted without change to *www.regulations.gov* including any personal information provided. To confirm receipt of your comment(s) please check *www.regulations.gov* approximately two to three days after submission to verify posting (except allow for 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Shelly Hammond, *shammond@abilityone.gov,* (571) 457–9468.

SUPPLEMENTARY INFORMATION:

I. Background

The Committee's last rule making administrative changes was published in the **Federal Register** at June 2, 2000, at 65 FR 35286.

The Committee seeks to provide the following administrative changes based on changes to the Office of the Federal Register's language and processes. The Commission seeks to remove mailing address and add email address for the Committee and Central Nonprofit Agencies.

This proposed rule would update the Committee's regulations in 41 CFR chapter 51–1.1—51–10.101 to reflect those statutory changes.

II. Changes Proposed by the Committee in This Rulemaking

This proposed rule amends the Committee's regulations to include the following administrative changes:

III. Expected Impact of the Proposed Rule

This rulemaking is not expected to have a significant impact on small businesses.

IV. Regulatory Procedures

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

This proposed rule is not a significant regulatory action, under E.O. 12866.

Executive Order 13771—Reducing Regulations and Controlling Regulatory Costs

This proposed rule is not expected to be an E.O. 13771 deregulatory action.

Regulatory Flexibility Act

It has been certified that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This proposed rule does not contain an information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments.

List of Subjects

41 CFR Part 51–1

Government procurement, Individuals with disabilities.

41 CFR Part 51–2

Government procurement, Individuals with disabilities, Organization and functions (Government agencies).

41 CFR Part 51–3

Government procurement, Individuals with disabilities.

41 CFR Part 51–4

Government procurement, Individuals with disabilities, Reporting and recordkeeping requirements.

41 CFR Parts 51–5 and 51–6

Government procurement, Individuals with disabilities.

41 CFR Part 51–7

Environmental impact statements.

41 CFR Part 51–8

Administrative practice and procedure, Archives and records, Confidential business information, Freedom of information, Privacy Act.

41 CFR Part 51–9

Privacy Act Rules.

41 CFR Part 51–10

Administrative practice and procedure, Civil rights, Equal employment opportunity, Federal buildings and facilities, Individuals with disabilities.

For reasons set forth in the preamble, the Committee proposes to amend 41 CFR parts 51–1 through 51–10 as follows:

■ 1. The authority citation for parts 51–1, 51–2, 51–3, 51–4, 51–5, 51–6, 51–7, 51–8, 51–9, and 51–10 continues to read as follows:

Authority: 41 U.S.C. 46–48c.

PART 51–1—GENERAL

■ 2. Revise § 51–1.1 to read as follows:

§ 51–1.1 Policy.

(a) It is the policy of the Government to increase employment and training opportunities for persons who are blind or have other severe disabilities through the purchase of products and services from qualified nonprofit agencies employing persons who are blind or have other severe disabilities. The Committee for Purchase from People Who Are Blind or Severely Disabled (hereinafter the Committee) was established by the Javits-Wagner-O'Day Act, Public Law [111–350, section 3, Jan. 4, 2011, 124 Stat. 3837], as amended and recodifies, 41 U.S.C. 8501–8506 (hereinafter the JWOD Act). The Committee is responsible for implementation of a comprehensive program designed to enforce this policy.

(b) It is the policy of the Committee to encourage all Federal entities and employees to provide the necessary support to ensure that the JWOD Act is implemented in an effective manner. This support includes purchase of products and services published on the Committee's Procurement List through appropriate channels from nonprofit agencies employing persons who are blind or have other severe disabilities designated by the Committee; recommendations to the Committee of new products and services suitable for addition to the Procurement List; and cooperation with the Committee and the central nonprofit agencies in the provision of such data as the Committee may decide is necessary to determine suitability for addition to the Procurement List.

■ 3. Revise § 51–1.2 to read as follows:

§ 51–1.2 Mandatory source priorities.

(a) The JWOD Act mandates that products or services on the Procurement List required by Government entities be procured, as prescribed in this regulation, from a nonprofit agency employing persons who are blind or have other severe disabilities, at a price established by the Committee, if that product or service is available within the normal period required by that Government entity. Except as provided in paragraph (b) of this section, the JWOD Act has priority, under the provisions of 41 U.S.C. 8504, over any other supplier of the Government's requirements for products and services on the Committee's Procurement List.

(b) Federal Prison Industries, Inc. has priority, under the provisions of 18 U.S.C. 4124 and 41 U.S.C. 8504(b), over nonprofit agencies employing persons who are blind or have other severe disabilities in furnishing products for sale to the Government. All or a portion of the Government's requirement for a product for which Federal Prison Industries, Inc. has exercised its priority may be added to the Procurement List. However, such addition is made with the understanding that procurement under the JWOD Act shall be limited to that portion of the Government's requirement for the product which is not available or not required to be procured from Federal Prison Industries, Inc.

(c) The JWOD Act requires the Committee to prescribe regulations providing that, in the purchase by the Government of products produced and offered for sale by qualified nonprofit agencies employing persons who are blind and nonprofit agencies employing persons who have other severe disabilities, priority shall be accorded to products produced and offered for sale by qualified nonprofit agencies for the blind. In approving the addition of products, to the Procurement List, the Committee accords priority to nonprofit agencies for the blind. Nonprofit agencies for the blind and nonprofit agencies employing persons with severe

disabilities have equal priority for services.

■ 4. Amend § 51–1.3 by:

■ a. Revising the definitions of ''AbilityOne Program,'' ''Central nonprofit agency,'' ''Committee'', Contracting activity'', ''Direct labor'', ''Interested person'', ''Military resale'', ''Nonprofit agency'', ''Participating nonprofit agency'', and ''Procurement List'';

■ b. Adding in alphabetical order a definition for ''Qualified nonprofit agency for other severely disabled'';

■ c. Removing the definition of ''Qualified nonprofit agency for other severely handicapped''; and

■ d. Revising the definition of ''Qualified nonprofit agency for the blind''.

The revisions and addition read as follows:

§ 51–1.3 Definitions.

* * * * *

AbilityOne Program means the program authorized by the JWOD Act to increase employment and training opportunities for persons who are blind or have other severe disabilities through Government purchasing of products and services from nonprofit agencies employing these persons.

* * * * *

Central nonprofit agency means an agency organized under the laws of the United States or of any State, operated in the interest of the blind or persons with other severe disabilities, the net income of which does not incur in whole or in part to the benefit of any shareholder or other individual, and designated by the Committee to facilitate the distribution (by direct allocation, subcontract, or any other means) of orders of the Government for products and services on the Procurement List among nonprofit agencies employing persons who are blind or have other severe disabilities, to provide information required by the Committee to implement the JWOD Program, and to otherwise assist the Committee in administering these regulations as set forth herein by the Committee.

Committee means the Committee for Purchase from People Who Are Blind or Severely Disabled.

Contracting activity means any element of an entity of the Government that has responsibility for identifying and/or procuring Government requirements for products or services. Components of a contracting activity, such as a contracting office and an ordering office, are incorporated in this definition, which includes all offices within the definitions of ''contracting activity,'' ''contracting office,'' and ''contract administration office'' contained in the Federal Acquisition Regulation, 48 CFR 2.101.

Direct labor means all work required for preparation, processing, and packing of a product or work directly related to the performance of a service, but not supervision, administration, inspection or shipping.

* * * * *

Interested person means an individual or legal entity affected by a proposed addition of a product or service to the Procurement List or a deletion from it.

Military resale products means products on the Procurement List sold for the private, individual use of authorized patrons of Armed Forces commissaries and exchanges, or like activities of other Government departments and agencies.

Nonprofit agency (formerly workshop) means a nonprofit agency serving people who are blind or a nonprofit agency employing persons with severe disabilities, as appropriate.

* * * * *

Participating nonprofit agency (formerly participating workshop) means any nonprofit agency which has been authorized by the Committee to furnish a product or service to the Government under the JWOD Act.

Procurement List means a list of products (including military resale products) and services which the Committee has determined to be suitable to be furnished to the Government by nonprofit agencies for the blind or nonprofit agencies employing persons with severe disabilities pursuant to the JWOD Act and these regulations.

Qualified nonprofit agency for other severely disabled (formerly workshop for other severely handicapped) means an agency organized under the laws of the United States or any State, operated in the interests of persons with severe disabilities who are not blind, and the net income of which does not inure in whole or in part to the benefit of any shareholder or other individual; which complies with applicable occupational health and safety standards prescribed by the Secretary of Labor; and which in furnishing products and services (whether or not the products or services are procured under these regulations) during the fiscal year employs persons with severe disabilities (including blind) for not less than 75 percent of the work-hours of direct labor required to furnish such products or services.

Qualified nonprofit agency for the blind (hereinafter nonprofit agency for the blind) (formerly workshop for the blind) means an agency organized under the laws of the United States or of any State, operated in the interest of blind individuals, and the net income of which does not inure in whole or in part to the benefit of any shareholder or other individual; which complies with applicable occupational health and safety standards prescribed by the Secretary of Labor; and which in furnishing products and services (whether or not the products or services are procured under these regulations) during the fiscal year employs blind individuals for not less than 75 percent of the work-hours of direct labor required to furnish such products or services.

* * * * *

PART 51–2—COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

■ 5. Revise § 51–2.2 to read as follows:

§ 51–2.2 Powers and responsibilities.

The Committee is responsible for carrying out the following functions in support of its mission of providing employment and training opportunities for persons who are blind or have other severe disabilities and, whenever possible, preparing those individuals to engage in competitive employment:

(a) Establish rules, regulations, and policies to assure effective implementation of the JWOD Act.

(b) Determine which product and services procured by the Federal Government are suitable to be furnished by qualified nonprofit agencies employing persons who are blind or have other severe disabilities and add those items to the Committee's Procurement List. Publish notices of addition to the Procurement List in the **Federal Register**. Disseminate information on Procurement List items to Federal agencies. Delete items no longer suitable to be furnished by nonprofit agencies. Authorize and deauthorize central nonprofit agencies and nonprofit agencies to accept orders from contracting activities for the furnishing of specific products and services on the Procurement List.

(c) Determine fair market prices for items added to the Procurement List and revise those prices in accordance with changing market conditions to assure that the prices established are reflective of the market.

(d) Monitor nonprofit agency compliance with Committee regulations and procedures.

(e) Inform Federal agencies about the AbilityOne Program and the statutory mandate that items on the Procurement

List be purchased from qualified nonprofit agencies, and encourage and assist entities of the Federal Government to identify additional products and services that can be purchased from qualified nonprofit agencies. To the extent possible, monitor Federal agencies' compliance with JWOD requirements.

(f) Designate, set appropriate ceilings on fee paid to these central nonprofit agencies by nonprofit agencies selling items under the AbilityOne Program, and provide guidance to central nonprofit agencies engaged in facilitating the distribution of Government orders and helping State and private nonprofit agencies participate in the AbilityOne Program.

(g) Conduct a continuing study and evaluation of its activities under the JWOD Act for the purpose of assuring effective and efficient administration of the JWOD Act. The Committee may study, independently, or in cooperation with other public or nonprofit private agencies, problems relating to:

(1) The employment of the blind or individuals with other severe disabilities.

(2) The development and adaptation of production methods which would enable a greater utilization of these individuals.

(h) Provide technical assistance to the central nonprofit agencies and the nonprofit agencies to contribute to the successful implementation of the JWOD Act.

(i) Assure that nonprofit agencies employing persons who are blind will have priority over nonprofit agencies employing persons with severe disabilities in furnishing products.

■ 6. Revise § 51–2.3 to read as follows:

§ 51–2.3 Notice of proposed addition or deletion.

At least 30 days prior to the Committee's consideration of the addition or deletion of a product or service to or from the Procurement List, the Committee publishes a notice in the **Federal Register** announcing the proposed addition or deletion and providing interested persons an opportunity to submit written data or comments on the proposal. Interested persons submitting comments in bound form should also submit an unbound copy that is capable of being legibly photocopied.

■ 7. Revise § 51–2.4 to read as follows:

§ 51–2.4 Determination of suitability.

(a) For a product or service to be suitable for addition to the Procurement List, each of the following criteria must be satisfied:

(1) *Employment potential.* The proposed addition must demonstrate a potential to generate employment for persons who are blind or have other severe disabilities.

(2) *Nonprofit agency qualifications.* The nonprofit agency (or agencies) proposing to furnish the item must qualify as a nonprofit agency serving persons who are blind or have other severe disabilities, as set forth in part 51–4 of this chapter.

(3) *Capability.* The nonprofit agency (or agencies) desiring to furnish a product or service under the JWOD Program must satisfy the Committee as to the extent of the labor operations to be performed and that it will have the capability to meet Government quality standards and delivery schedules by the time it assumes responsibility for supplying the Government.

(4) *Level of impact on the current contractor for the product or service.* (i) In deciding whether or not a proposed addition to the Procurement List is likely to have a severe adverse impact on the current contractor for the specific product or service, the Committee gives particular attention to:

(A) The possible impact on the contractor's total sales, including the sales of affiliated companies and parent corporations. In addition, the Committee considers the effects of previous Committee actions.

(B) Whether that contractor has been a continuous supplier to the Government of the specific product or service proposed for addition and is, therefore, more dependent on the income from such sales to the Government.

(ii) If there is not a current contract for the product or service being proposed for addition to the Procurement List, the Committee may consider the most recent contractor to furnish the item to the Government as the current contractor for the purpose of determining the level of impact.

(b) In determining the suitability of a product or service for addition to the Procurement List, the Committee also considers other information it deems pertinent, including comments on a proposal published in the **Federal Register** to add the product or service to the Procurement List and information submitted by Government personnel and interested persons. Because the Committee's authority to establish fair market prices is separate from its authority to determine the suitability of a product or service for addition to the Procurement List, the Committee does not consider comments on proposed fair market prices for products and services proposed for addition to the Procurement List to be pertinent to a suitability determination.

■ 8. Revise § 51–2.5 to read as follows:

§ 51–2.5 Committee decision.

The Committee considers the particular facts and circumstances in each case in determining if a product or service is suitable for addition to the Procurement List. When the Committee determines that a proposed addition is likely to have a severe adverse impact on a current contractor, it takes this fact into consideration in deciding not to add the product or service to the Procurement List, or to add only a portion of the Government requirement for the item. If the Committee decides to add a product or service in whole or in part to the Procurement List, that decision is announced in the **Federal Register** with a notice that includes information on the effective date of the addition.

■ 9. Amend § 51–2.7 by revising paragraphs (a) and (c) to read as follows:

§ 51–2.7 Fair market price.

(a) The Committee is responsible for determining fair market prices, and changes thereto, for products and services on the Procurement List. The Committee establishes an initial fair market price at the time a product or service is added to the Procurement List. This initial price is based on Committee procedures, which permit negotiations between the contracting activity and the nonprofit agency which will produce or provide the product or service to the Government, assisted by the appropriate central nonprofit agency. If agreed to by the negotiating parties, the initial price may be developed using other methodologies specified in Committee pricing procedures.

* * * * *

(c) Recommendations for initial fair market prices, or changes thereto, shall be submitted jointly by the contracting activities and nonprofit agencies concerned to the appropriate central nonprofit agency. After review and analysis, the central nonprofit agency shall submit the recommended prices and methods by which prices shall be changed to the Committee, along with the information required by Committee pricing procedures to support each recommendation. The Committee will review the recommendations, revise the recommended prices where appropriate, and establish a fair market price, or change thereto, for each product or service which is the subject of a recommendation.

■ 10. Amend § 51–2.8 by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 51–2.8 Procurement List.

(a) The Committee maintains a Procurement List which includes the products and services which shall be procured by Government departments and agencies under the JWOD Act from the nonprofit agency(ies) designated by the Committee. Copies of the Procurement List, together with information on procurement requirements and procedures, are available at the Committee's website: *https://www.abilityone.gov.*

(b) For products, including military resale products, the Procurement List identifies the name and national stock number or item designation for each product, and where appropriate, any limitation on the portion of the product which must be procured under the JWOD Act.

* * * * *

PART 51–3—CENTRAL NONPROFIT AGENCIES

■ 11. Revise § 51–3.1 to read as follows:

§ 51–3.1 General.

Under the provisions of section 2(c) of the JWOD Act, the Committee designates Central Nonprofit Agency(ies) (CNAs) through a separate written agreement approved by vote of the Commission. The list of the current central nonprofit agency(ies) designated by the Committee is available at the Committee's website: *https://www.abilityone.gov.*

■ 12. Amend § 51–3.2 by revising paragraphs (c), (d), (e), (h), (i), (k), and (l) to read as follows:

§ 51–3.2 Responsibilities under the AbilityOne Program.

* * * * *

(c) Obtain from Federal contracting activities such procurement information as is required by the Committee to:

(1) Determine the suitability of a product or service being recommended to the Committee for addition to the Procurement List; and

(2) Establish an initial fair market price for a product or service or make changes in the fair market price.

(d) Recommend to the Committee, with the supporting information required by Committee policy or procedures, suitable products or services for procurement from its nonprofit agencies.

(e) Recommend to the Committee, with the supporting information required by Committee policy or procedures, initial fair market prices for products or services proposed for addition to the Procurement List.

* * * * *

(h) Oversee and assist its nonprofit agencies to ensure contract compliance in furnishing a product or a service.

(i) As market conditions change, recommend price changes with appropriate justification for assigned products or services on the Procurement List.

* * * * *

(k) When authorized by the Committee, enter into contracts with Federal contracting activities for the furnishing of products or services provided by its nonprofit agencies.

(l) At the time designated by the Committee, submit a completed, original copy of the appropriate Initial Representations and Certification(s) for the nonprofit agency concerned. This requirement does not apply to a nonprofit agency that is already authorized to furnish a product or service under the JWOD Act.

* * * * *

■ 13. Revise § 51–3.3 to read as follows:

§ 51–3.3 Assignment of product or service.

(a) The central nonprofit agencies shall determine by mutual agreement the assignment to one of them of a product or service for the purpose of evaluating its potential for possible future addition to the Procurement List, except that the Committee shall initially assign a product to a central nonprofit agency for the blind when a central nonprofit agency for other severely disabled has expressed an interest in the product and a central nonprofit agency for the blind has exercised the blind priority.

(b) Central nonprofit agencies for other severely disabled shall provide a central nonprofit agency for the blind with procurement information necessary for a decision to exercise or waive the blind priority when it requests a decision. A central nonprofit agency for the blind shall normally notify an interested central nonprofit agency of its decision within 30 days, but not later than 60 days after receipt of the procurement information, unless the central nonprofit agencies agree to an extension of time for the decision. Disagreements on extensions shall be referred to the Committee for resolution.

(c) If a central nonprofit agency for the blind exercises the blind priority for a product, it shall immediately notify the Committee and any other central nonprofit agency and shall submit to the Committee a proposal to add the product to the Procurement List within nine months of the notification, unless the Committee extends the assignment period because of delays beyond the control of the central nonprofit agency for the blind. Upon expiration of the assignment period, the Committee shall reassign the product to another central nonprofit agency.

(d) The central nonprofit agency assigned a product shall, consistent with 41 U.S.C. 8504(b) and 41 CFR 51–6.2(d), confirm that the contracting activity obtain a decision from Federal Prison Industries on the exercise or waiver of its priority, including submitting the procurement information required by Federal Prison Industries when it requests the decision. Federal Prison Industries shall normally notify the contracting activity of its decision within 30 days, but not later than 60 days after receipt of the procurement information, unless it agrees with the contracting activity on an extension of time for the decision. The contracting activity shall notify the central nonprofit agency of any disagreements with Federal Prison Industries and the central nonprofit agency shall refer a disagreement over an extension to the Committee for resolution with Federal Prison Industries.

(e) The central nonprofit agency shall provide the Committee the decision of Federal Prison Industries on the waiver or exercise of its priority when it requests the addition of the product to the Procurement List. The central nonprofit agency shall also provide the decision of a central nonprofit agency for the blind waiving its priority.

■ 14. Revise § 51–3.4 to read as follows:

§ 51–3.4 Distribution of orders.

Central nonprofit agencies shall distribute orders from the Government only to nonprofit agencies which the Committee has approved to furnish the specific product or service. When the Committee has approved two or more nonprofit agencies to furnish a specific product or service, the central nonprofit agency shall distribute orders among those nonprofit agencies in a fair and equitable manner.

PART 51–4—NONPROFIT AGENCIES

■ 15. Amend § 51–4.3 by revising paragraphs (a), (b) introductory text, and (b)(1) and (9) to read as follows:

§ 51–4.3 Maintaining qualification.

(a) To maintain its qualification under the JWOD Act, each nonprofit agency authorized to furnish a product or a service shall continue to comply with the requirements of a ''nonprofit agency for other severely disabled'' or a ''nonprofit agency for the blind'' as defined in § 51–1.3 of this chapter. In

addition, each such nonprofit agency must submit to its central nonprofit agency by November 1 of each year, two completed copies of the appropriate Annual Representations and Certifications covering the fiscal year ending the preceding September 30.

(b) In addition to paragraph (a) of this section, each nonprofit agency participating in the Ability One Program shall:

(1) Furnish products or services in strict accordance with Government orders.

* * * * *

(9) Upon receipt of payment by the Government for products or services furnished under the Ability One Program, pay to the central nonprofit agency a fee which meets the requirements of § 51–3.5 of this chapter.

* * * * *

■ 16. Amend § 51–4.4 by revising paragraphs (a) through (c) to read as follows:

§ 51–4.4 Subcontracting.

(a) Nonprofit agencies shall seek broad competition in the purchase of materials and components used in the products and services furnished to the Government under the JWOD Act. Nonprofit agencies shall inform the Committee, through their central nonprofit agency, before entering into multiyear contracts for materials or components used in the products and services furnished to the Government under the JWOD Act.

(b) Each nonprofit agency shall accomplish the maximum amount of subcontracting with other nonprofit agencies and small business concerns that the nonprofit agency finds to be consistent both with efficient performance in furnishing products or services under the JWOD Act and maximizing employment for persons who are blind or have other severe disabilities.

(c) Nonprofit agencies may subcontract a portion of the process for producing a product or providing a service on the Procurement List provided that the portion of the process retained by the prime nonprofit agency generates employment for persons who are blind or have other severe disabilities. Subcontracting intended to be a routine part of the production of a product or provision of a service shall be identified to the Committee at the time the product or service is proposed for addition to the Procurement List and any significant changes in the extent of subcontracting must be approved in advance by the Committee.

* * * * *

PART 51–5—CONTRACTING REQUIREMENTS

■ 17. Revise § 51–5.1 to read as follows:

§ 51–5.1 General.

(a) Contracting activities are encouraged to assist the Committee and the central nonprofit agencies in identifying suitable products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities so that the Committee can attain its objective of increasing employment and training opportunities for individuals who are blind or have other severe disabilities. For items which appear to be suitable to be furnished by nonprofit agencies, the contracting activity should refer the candidate products and services to the Committee or a central nonprofit agency. If a contracting activity decides to procure one or more products which are similar to a product or products on the Procurement List, the contracting activity should refer the products it intends to procure to the Committee or a central nonprofit agency.

(b) Contracting activities shall provide the Committee and designated central nonprofit agencies with information needed to enable the Committee to determine whether a product or service is suitable to be furnished by a nonprofit agency. For products, information such as the latest solicitation and amendments, bid abstracts, procurement history, estimated annual usage quantities, and anticipated date of next solicitation issuance and opening may be needed. For services, similar information including the statement of work and applicable wage determination may be required. In order to assist in evaluating the suitability of an Office of Management and Budget Circular No. A–76 conversion, contracting activities should provide a copy of the draft statement of work and applicable wage determination to the central nonprofit agency upon its request.

■ 18. Amend § 51–5.2 by revising paragraphs (a) through (d) to read as follows:

§ 51–5.2 Mandatory source requirement.

(a) As provided in 41 U.S.C. 8504, entities of the Federal Government intending to procure products or services on the Procurement List shall procure such products and services from nonprofit agencies authorized by the Committee. The only exception to this mandatory requirement is for products available from the Federal Prison Industries, Inc., which has a purchase priority over products on the Procurement List.

(b) Purchases of products on the Procurement List by entities of the Government shall be made from sources authorized by the Committee. These sources may include nonprofit agencies, central nonprofit agencies when approved by the Committee, Government central supply agencies such as the Defense Logistics Agency and the General Services Administration, and certain commercial distributors. As noted in § 51–6.2 of this chapter, identification of the authorized sources for a particular product may be obtained from the central nonprofit agencies indicated on the Procurement List which is found at *www.abilityone.gov.*

(c) Contracting activities shall require other persons providing products which are on the Procurement List to entities of the Government by contract to order these products from the sources authorized by the Committee.

(d) Procedures for obtaining military resale products are contained in § 51–6.4 of this chapter.

* * * * *

■ 19. Amend § 51–5.3 by revising paragraphs (a) and (c) to read as follows:

§ 51–5.3 Scope of requirement.

(a) When a product is included on the Procurement List, the mandatory source requirement covers the National Stock Number or item designation listed and products that are essentially the same as the listed item. In some instances, only a portion of the Government requirement for a National Stock Number or item designation is specified by the Procurement List. Where geographic areas, quantities, percentages or specific supply locations for a product are listed, the mandatory provisions of the JWOD Act apply only to the portion or portions of the product indicated by the Procurement List.

* * * * *

(c) When a product or service is added to the Procurement List, the addition does not affect contracts for the product or service awarded prior to the effective date of the Procurement List addition or options exercised under those contracts.

■ 20. Amend § 51–5.4 by revising paragraphs (a)(1) and (2) to read as follows:

§ 51–5.4 Purchase exceptions.

(a) * * *

(1) The central nonprofit agency or its nonprofit agency(ies) cannot furnish a product or service within the period specified, and

(2) The product or service is available from commercial sources in the quantities needed and significantly sooner than it will be available from the nonprofit agency(ies).

* * * * *

■ 21. Amend § 51–5.5 by revising paragraphs (a), (b), (c), and (e) to read as follows:

§ 51–5.5 Prices.

(a) The prices for items on the Procurement List are fair market prices established by the Committee under authority of the Javits-Wagner-O'Day Act (41 U.S.C. 8503(b)]).

(b) Prices for products include applicable packaging, packing, and marking. Prices include transportation to point of delivery as specified in § 51–5.6.

(c) Price changes for products and services shall usually apply to orders received by the nonprofit agency on or after the effective date of the change. In special cases, after considering the views of the contracting activity, the Committee may make price changes applicable to orders received by the nonprofit agency prior to the effective date of the change.

* * * * *

(e) If a contracting activity desires packing, packaging, or marking of products other than the standard pack or as provided in the Procurement List, any difference in cost shall be negotiated with the nonprofit agency.

■ 22. Revise § 51–5.6 to read as follows:

§ 51–5.6 Shipping.

(a) Except as provided in paragraph (b) of this section, products are sold to the Government on an ''F.O.B. destination'' basis, with delivery being accomplished when the shipment reaches the facility designated by the contracting activity. Time of delivery is when the shipment is released by the carrier and accepted by the contracting activity or its agent. In this delivery method, the nonprofit agency will normally use commercial bills of lading and will be responsible for any loss or damage to the goods occurring before the products reach the designated delivery point. The nonprofit agency will prepare and distribute commercial bills of lading, furnish delivery schedules, designate the carriers, and pay all shipping charges to specified delivery points.

(b) The Committee may determine that certain products are to be sold to the Government on an ''F.O.B. origin'' basis, with delivery being accomplished when a shipment is placed aboard the vehicle of the initial carrier. Time of delivery is when the shipment is released to and accepted by the initial carrier. In this delivery method, the nonprofit agency will normally use Government bills of lading, and responsibility for loss or damage to the goods while in transit passes to the Government at the time the initial carrier accepts a shipment. If the contracting activity fails to furnish a Government bill of lading promptly, such failure shall be considered an excusable delay in delivery.

■ 23. Revise § 51–5.7 to read as follows:

§ 51–5.7 Payments.

Payments for products or services of persons who are blind or have other severe disabilities shall be made within 30 days after shipment or receipt of a proper invoice or voucher.

PART 51–6—PROCUREMENT PROCEDURES

■ 24. Amend § 51–6.1 by revising paragraphs (a) and (c) to read as follows:

§ 51–6.1 Direct order process.

(a) Once a product or service is added to the Procurement List, the central nonprofit agency may authorize the contracting activity to issue orders directly to a nonprofit agency without requesting an allocation for each order. This procedure is known as the direct order process.

* * * * *

(c) An order for products or services shall provide leadtime sufficient for purchase of materials, production or preparation, and delivery or completion.

* * * * *

■ 25. Amend § 51–6.2 by revising paragraphs (a), (b) introductory text, (b)(1), (c), (d), (g), (i), and (k) to read as follows:

51–6.2 Allocation process.

(a) In those cases where a direct order authorization has not been issued as described in § 51–6.1, the contracting activity shall submit written requests for allocation to the appropriate central nonprofit agency indicated by the Procurement List which is found at the Committee's website: *https://www.abilityone.gov.*

(b) Requests for allocations shall contain, as a minimum:

(1) For products. Name, stock number, latest specification, quantity, unit price, and place and time of delivery.

* * * * *

(c) Contracting activities shall request allocations in sufficient time for the central nonprofit agency to reply, for the order(s) to be placed, and for the nonprofit agencies to furnish the product or service (*see* paragraph (i) of this section).

(d) When a product on the Procurement List also appears on the Federal Prison Industries' ''Schedule of Products,'' the contracting activity shall obtain clearance from the Federal Prison Industries prior to requesting an allocation or placing an order directly to the nonprofit agency(ies).

* * * * *

(g) An allocation is not an obligation to supply a product or service, or an obligation for the contracting activity to issue an order. Nonprofit agencies are not authorized to commence production until receipt of an order.

* * * * *

(i) An order for products or services shall provide leadtime sufficient for purchase of materials, production or preparation, and delivery or completion.

* * * * *

(k) In those instances where the central nonprofit agency is the prime contractor rather than the nonprofit agency, the central nonprofit agency will designate the nonprofit agency(ies) authorized by the Committee to furnish definite quantities of products or specific services upon receipt of an order from the contracting activity.

■ 26. Revise § 51–6.3 to read as follows:

§ 51–6.3 Long-term procurements.

(a) Contracting activities are encouraged to investigate long-term ordering agreements for products listed on the Procurement List to level off demand, thereby helping ensure stability of employment and development of job skills for persons who are blind or have other severe disabilities.

(b) Contracting activities are encouraged to use the longest contract term available by law to their agencies for contracts for products and services under the AbilityOne Program, in order to minimize the time and expense devoted to formation and renewal of these contracts.

■ 27. Revise § 51–6.4 to read as follows:

§ 51–6.4 Military resale products.

(a) Purchase procedures for ordering military resale products are available from the central nonprofit agencies. Authorized resale outlets (military commissary stores, Armed Forces exchanges and like activities of other Government departments and agencies) shall request the central nonprofit agency responsible for the military resale product being ordered to designate the nonprofit agency or its agent to which the outlets shall forward orders.

(b) Authorized resale outlets shall stock military resale products in as

broad a range as practicable. Authorized resale outlets may stock commercial items comparable to military resale products they stock, except that military commissary stores shall stock military resale products in the 300–800–, 900–, 1000–, 1100–, 10000– (10000–10999); 13000 (13000–13999); 14000 (14000–14999); 15000 (15000–15999); and 16000 (16000–16999) series exclusively, unless an exception has been granted on an individual store basis for the stocking of comparable commercial items for which there is a significant customer demand.

(c) The Defense Commissary Agency shall, after consultation with the Committee:

(1) Establish mandatory lists of military resale products to be stocked in commissary stores.

(2) Require the stocking in commissary stores of military resale products in the 0– (0–99), 200–, 300–, 400–, 500–, 600–, 700–, 800–, 900–, 1000–, 1100–, 1200- (1200–9999), 10000- (10000–10999), 11000 (11000–11999); 12000 (12000–12999); 13000 (13000–13999); 14000 (14000–14999); 15000 (15000–15999); and 16000 (16000–16999) series in as broad a range as is practicable.

(3) Issue guidance requiring commissary store personnel to maximize sales potential of military resale products.

(4) Establish policies and procedures which reserve to its agency headquarters the authority to grant exceptions to the exclusive stocking of 300–, 800–, 900–, 1000–, 1100–, 10000– (10000–10999); 13000 (13000–13999); 14000 (14000–14999); 15000 (15000–15999); and 16000 (16000–16999) series military resale products.

(d) The Defense Commissary Agency shall provide the Committee a copy of each directive which relates to the stocking of military resale products in commissary stores, including exceptions authorizing the stocking of commercial items in competition with 300–, 800–, 900–, 1000–, 1100–, 10000- (10000–10999); 13000 (13000–13999); 14000 (14000–14999); 15000 (15000–15999); and 16000 (16000–16999) series military resale products.

(e) The prices of military resale products include delivery to destination or, in the case of destinations overseas, to designated depots at ports of embarkation. Zone pricing is used for delivery to Alaska and Hawaii.

■ 28. Amend § 51–6.6. by revising paragraph (a) to read as follows:

§ 51–6.6 Request for waiver of specification requirement.

(a) Nonprofit agencies and central nonprofit agencies are encouraged to recommend changes to specification requirements or request waivers where there are opportunities to provide equal or improved products at a lower cost to the Government.

* * * * *

■ 29. Revise § 51–6.7 to read as follows:

§ 51–6.7 Orders in excess of nonprofit agency capability.

(a) Nonprofit agencies are expected to furnish products on the Procurement List within the time frames specified by the Government. The nonprofit agency must have the necessary production facilities to meet normal fluctuations in demand.

(b) Nonprofit agencies shall take those actions necessary to ensure that they can ship products within the time frames specified by the Government. In instances where the nonprofit agency determines that it cannot ship the product in the quantities specified by the required shipping date, it shall notify the central nonprofit agency and the contracting activity. The central nonprofit agency shall request a revision of the shipping schedule which the contracting activity should grant, if feasible, or the central nonprofit agency shall issue a purchase exception authorizing procurement from commercial sources as provided in § 51–5.4 of this chapter.

■ 30. Amend § 51–6.8 by revising paragraphs (a), (b), (c), and (e) to read as follows:

§ 51–6.8 Deletion of items from the Procurement List.

(a) When a central nonprofit agency decides to request that the Committee delete a product or service from the Procurement List, it shall notify the Committee staff immediately. Before reaching a decision to request a deletion of an item from the Procurement List, the central nonprofit agency shall determine that none of its nonprofit agencies is capable and desirous of furnishing the product or service involved.

(b) Except in cases where the Government is no longer procuring the item in question, the Committee shall, prior to deleting an item from the Procurement List, determine that none of the nonprofit agencies of any other central nonprofit agency is desirous and capable of furnishing the product or service involved.

(c) Nonprofit agencies will normally be required to complete production of any orders for products on hand regardless of the decision to delete the item. Nonprofit agencies shall obtain concurrence of the contracting activity and the Committee prior to returning a purchase order to the contracting activity.

* * * * *

(e) The Committee may delete an item from the Procurement List without a request from a central nonprofit agency if the Committee determines that none of the nonprofit agencies participating in the AbilityOne Program are capable and desirous of furnishing the product or service to the Government, or if the Committee determines that the product or service is no longer suitable for procurement from nonprofit agencies employing people who are blind or have other severe disabilities. In considering such an action, the Committee will consult with the appropriate central nonprofit agency, the nonprofit agency or agencies involved, and the contracting activity.

■ 31. Revise § 51–6.9 to read as follows:

§ 51–6.9 Correspondence and inquiries.

Routine contracting activity correspondence or inquiries concerning deliveries of products being shipped from or performance of services by nonprofit agencies employing persons who are blind or have other severe disabilities shall be with the nonprofit agency involved. Major problems shall be referred to the appropriate central nonprofit agency. In those instances, where the problem cannot be resolved by the central nonprofit agency and the contracting activity involved, the contracting activity or central nonprofit agency shall notify the Committee of the problem so that action can be taken by the Committee to resolve it.

■ 32. Amend § 51–6.10 by revising paragraph (a) to read as follows:

§ 51–6.10 Quality of merchandise.

(a) Products furnished under Government specification by nonprofit agencies employing persons who are blind or have other severe disabilities shall be manufactured in strict compliance with such specifications. Where no specifications exist, products furnished shall be of a quality equal to or higher than similar items available on the commercial market. Products shall be inspected utilizing nationally recognized test methods and procedures for sampling and inspection.

* * * * *

■ 33. Amend § 51–6.11 by revising paragraph (a) to read as follows:

§ 51–6.11 Quality complaints.

(a) When the quality of a product received is not considered satisfactory

by the using activity, the activity shall take the following actions as appropriate:

(1) For products received from Defense Logistics Agency supply centers, General Services Administration supply distribution facilities, Department of Veterans Affairs distribution division or other central stockage depots, or specifically authorized supply source, notify the supplying agency in writing in accordance with that agency's procedures. The supplying agency shall, in turn, provide copies of the notice to the nonprofit agency involved and its central nonprofit agency.

(2) For products received directly from nonprofit agencies employing persons who are blind or have other severe disabilities, address complaints to the nonprofit agency involved with a copy to the central nonprofit agency with which it is affiliated.

* * * * *

■ 34. Amend § 51–6.12 by revising paragraphs (a), (b), and (e) to read as follows:

§ 51–6.12 Specification changes and similar actions.

(a) Contracting activities shall notify the nonprofit agency or agencies authorized to furnish a product on the Procurement List and the central nonprofit agency concerned of any changes to the specification or other description of the product.

(b) When a government entity is changing the specification or description of a product on the Procurement List, including a change that involves the assignment of a new national stock number or item designation, the office assigned responsibility for the action shall obtain the comments of the Committee and the central nonprofit agency concerned on the proposed change and shall notify the nonprofit agency and the central nonprofit agency concerned at least 90 days prior to placing an order for a product covered by the new specification or description.

* * * * *

(e) Nonprofit agencies shall recommend changes in specifications, item descriptions, and statements of work that will improve the product or service being provided, reduce costs, or improve overall value to the Government. Contracting activities shall respond promptly to these recommendations and work with the nonprofit agencies to implement them when appropriate.

■ 35. Revise § 51–6.13 to read as follows:

§ 51–6.13 Replacement and similar products.

(a) When a product on the Procurement List is replaced by another product which has not been recently procured, and a nonprofit agency can furnish the replacement product in accordance with the Government's quality standards and delivery schedules, the replacement product is automatically considered to be on the Procurement List and shall be procured from the nonprofit agency designated by the Committee at the fair market price the Committee has set for the replacement product. The product being replaced shall continue to be included on the Procurement List until there is no longer a Government requirement for that product.

(b) If contracting activities desire to procure additional sizes, colors, or other variations of a product after the product is added to the Procurement List, and these similar products have not recently been procured, these products are also automatically considered to be on the Procurement List.

(c) In accordance with § 51–5.3 of this chapter, contracting activities are not permitted to purchase commercial items that are essentially the same as products on the Procurement List.

PART 51–7—PROCEDURES FOR ENVIRONMENTAL ANALYSIS

■ 36. Amend § 51–7.1 by revising paragraph (b) to read as follows:

§ 51–7.1 Purpose and scope.

* * * * *

(b) *Scope.* This part applies to all actions of the Committee for Purchase from Persons Who Are Blind or Severely Disabled which may affect environmental quality in the United States.

■ 37. Amend § 51–7.2 by revising paragraph (a) to read as follows:

§ 51–7.2 Early involvement in private, State, and local activities requiring Federal approval.

(a) 40 CFR 1501.2(d) requires agencies to provide for early involvement in actions which, while planned by private applicants or other non-Federal entities, require some sort of Federal approval. Pursuant to the JWOD Act (41 U.S.C. 8501–8506), the Committee for Purchase from People Who Are Blind or Severely Disabled makes the determination as to which qualified nonprofit agency serving persons who are blind or have other severe disabilities will furnish designated products and services to the Government.

* * * * *

PART 51–8—PUBLIC AVAILABILTY OF AGENCY MATERIALS

■ 38. Amend § 51–8.4 by revising the section heading and adding paragraph (g) to read as follows:

§ 51–8.4 Responsibility for responding to requests.

* * * * *

(g) *Appointments.* Material described in 5 U.S.C. 552(a)(2) shall be available for inspection during normal business hours at the Committee's offices. An individual who intends to visit the Committee offices to inspect this material shall make an appointment with the Executive Director at least one week in advance, except when the Committee has provided notification to the individual that the material is available for inspection in the Committee offices, in which case an appointment must be made at least 24 hours in advance. Appointments can be requested at the Committee's email address: *info@abilityone.gov.*

■ 39. Amend § 51–8.5 by adding paragraph (a) introductory text and revising paragraph (a)(1) to read as follows:

§ 51–8.5 Timing of Responses to Requests.

(a) *In general.* Requests to obtain copies of any material maintained by the Committee must be submitted to the Executive Director at the Committee's offices, email address: *info@abilityone.gov.* The requester may in his or her petition ask for a fee waiver if there is likely to be a charge for the requested information. All requests for records shall be deemed to have been made pursuant to the FOIA, regardless of whether the Act is specifically mentioned. Failure to submit a request in accordance with these procedures may delay the processing of the request.

(1) The Committee ordinarily will respond to requests according to their order of receipt. The time limits prescribed in the FOIA will begin only after the Committee identifies a request as being made under the FOIA and deemed received by the Committee.

* * * * *

PART 51–9—PRIVACY ACT RULES

■ 40. Revise § 51–9.301 to read as follows:

§ 51–9.301 Notification.

Any individual who wishes to determine if a system of records maintained by the Committee contains a record pertaining to him should direct a request to the Executive Director at the address indicated in the public notice or

at the Committee's email address: *info@abilityone.gov* describing the system of records which has been published in the **Federal Register**. The request should display clearly the legend ''Privacy Act Request'' on the face of the request letter. The request letter should contain the complete name and identifying number of the system as published in the **Federal Register**; the full name, address, and telephone number of the subject individual; a brief description of the nature, time, place and circumstances of the individual's association with the Committee and any other information which the individual believes would facilitate the Executive Director's determination whether the individual's name is included in the system of records. The Executive Director shall answer or acknowledge the request within ten working days.

■ 41. Amend § 51–9.301–1 by revising paragraphs (b) and (c) to read as follows:

§ 51–9.303–1 Form of requests.

* * * * *

(b) A written request should be directed to the Executive Director as listed in the public notice describing the system of records or at the Committee's email address: *info@abilityone.gov.* The individual should display clearly on the face of the request letter and on the face of the envelope the legend ''Privacy Act Request'', and include the complete name and identifying number of the system as published in the **Federal Register**; the full name, address, the telephone number of the individual; a brief description of the nature, time, place and circumstances of the individual's association with the Committee; and any other information which the individual believes would facilitate the Executive Director's search for the record.

(c) An individual who wishes to have a person of his choosing accompany him in reviewing a record must sign a statement authorizing the disclosure of his record in the presence of another individual, if so requested by the Executive Director. An individual who intends to visit the Committee office in order to review a record should make an appointment with the Executive Director using the Committee's email address at: *info@abilityone.gov* at least one week in advance.

■ 42. Revise § 51–9.304–4 to read as follows:

§ 51–9.304–4 Form of payment.

Payment shall be by check or money order payable to the Committee for Purchase from People Who Are Blind or Severely Disabled and shall be addressed to the Executive Director.

■ 43. Amend § 51–9.401 by revising paragraph (a) to read as follows:

§ 51–9.401 Submission of requests to amend records.

(a) An individual who desires to amend any record or information pertaining to him should direct a written request to the Executive Director, Committee for Purchase From People Who Are Blind or Severely Disabled at the Committee's email address: *info@abilityone.gov.*

* * * * *

■ 44. Amend § 51–9.405 by revising paragraph (a) to read as follows:

§ 51–9.405 Request of review of refusal to amend a record.

(a) An individual who disagrees with the refusal to amend may appeal that refusal with the Committee. An individual should address a request for review of a refusal to amend any record, exclusive of a personnel record of a current Committee employee to the Chairperson, Committee for Purchase from People Who Are Blind or Severely Disabled at the Committee's email address: *info@abilityone.gov.*

* * * * *

PART 51–10—ENFORCEMENT OF NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

■ 45. Amend § 51–10.170 by revising paragraph (c) to read as follows:

§ 51–10.170 Compliance procedures.

* * * * *

(c) The Executive Director shall be responsible for coordinating the implementation of this section. Complaints may be sent to the Executive Director, Committee for Purchase from People Who Are Blind or Severely Disabled at the Committee's email address: *info@abilityone.gov.*

* * * * *

Michael R. Jurkowski,

Deputy Director, Business Operations.

[FR Doc. 2021–15154 Filed 7–22–21; 8:45 am]

BILLING CODE 6353–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket Nos. 20–36; Report No. 3178; FRS 37546]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: Petition for Reconsideration (Petition) has been filed in the Commission's rulemaking proceeding by Catherine Wang, on behalf of Shure Incorporated.

DATES: Oppositions to the Petition must be filed on or before August 9, 2021. Replies to an opposition must be filed on or before August 17, 2021.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Hugh VanTuyl, Office of Engineering and Technology Bureau, (202) 418–7506 or *Hugh.VanTuyl@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3178, released July 7, 2021. The full text of the Petition can be accessed online via the Commission's Electronic Comment Filing System at: *http://apps.fcc.gov/ecfs/.* The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: Unlicensed White Space Device Operations in the Television Bands, FCC 20–156, published at 86 FR 11490, February 25, 2021, in ET Docket No. 20–36. This document is being published pursuant to 47 CFR 1.429(e). *See also* 47 CFR 1.4(b)(1) and 1.429(f), (g).

Number of Petitions Filed: 1.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2021–15641 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 86, No. 139
Friday, July 23, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Renew an Information Collection

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Research Service's (ARS) intention to request an extension of a currently approved information collection, Form AD–761, USDA Patent License Application for Government Invention that expires October 31, 2022.

DATES: Comments must be received on or before September 21, 2021.

ADDRESSES: Comments may be sent to Diana D. Halsey, USDA, ARS, Office of Technology Transfer, 301–504–6905, *diana.halsey@usda.gov*.

FOR FURTHER INFORMATION CONTACT: Diana D. Halsey, USDA, ARS, Office of Technology Transfer, 301–504–6905, *diana.halsey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: USDA Patent License Application.

OMB Number: 0518–0003.

Expiration Date of Approval: October 31, 2022.

Type of Request: To extend a currently approved information collection.

Abstract: The USDA patent licensing program grants patent licenses to qualified businesses and individuals who wish to commercialize inventions arising from federally supported research. The objective of the program is to use the patent system to promote the utilization of inventions arising from such research. The licensing of federally owned inventions must be done in accordance with the terms, conditions and procedures prescribed under 37 CFR part 404. Application for a license must be addressed to the Federal agency having custody of the invention. Licenses may be granted only if the license applicant has supplied the Federal agency with a satisfactory plan for the development and marketing of the invention and with information about the applicant's capability to fulfill the plan. 37 CFR 404.8 sets forth the information which must be provided by a license applicant. For the convenience of the applicant, USDA has itemized the information needed on Form AD–761, and instructions for completing the form are provided to the applicant. The information submitted is used to determine whether the applicant has both a complete and sufficient plan for developing and marketing the invention and the necessary manufacturing, marketing, technical and financial resources to carry out the submitted plan.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 3 hours per response.

Description of Respondents: Businesses or other for profit individuals.

Estimated Number of Respondents: 75.

Frequency of Responses: One time per invention.

Estimated Total Annual Burden on Respondents: 225 hours.

This data will be collected under the authority of 44 U.S.C. 3506(c)(2)(A).

Copies of this information collection and related instructions can be obtained without charge from Diana D. Halsey, USDA, ARS, Office of Technology Transfer by calling 301–504–6905.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. Comments may be sent to *diana.halsey@usda.gov.* All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Brian T. Nakanishi,

Acting Deputy Assistant Administrator.

[FR Doc. 2021–15673 Filed 7–22–21; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

[Docket ID CCC–2021–0008]

Notice of Funds Availability (NOFA); Pandemic Assistance for Timber Harvesters and Haulers Program (PATHH)

AGENCY: Farm Service Agency, Department of Agriculture (USDA).

ACTION: Notification of funding availability.

SUMMARY: The Farm Service Agency (FSA) is announcing the availability of assistance for timber harvesting and timber hauling businesses impacted by the effects of the COVID–19 outbreak through PATHH. Timber harvesting and hauling businesses are also commonly referred to as loggers and truckers. This NOFA establishes provisions for FSA to provide direct payments to eligible applicants who have suffered a gross revenue loss of at least 10 percent for the period of January 1, 2020, through December 1, 2020, compared to the period of January 1, 2019, through December 1, 2019. The eligibility requirements, payment calculation, and application procedure for PATHH are included in this NOFA.

FOR FURTHER INFORMATION CONTACT: Jody Kenworthy; telephone: (202) 690–5230; email: *Jody.Kenworthy@usda.gov.* Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

FSA will provide assistance to timber harvesting or timber hauling businesses for losses due to the COVID–19 pandemic. FSA is implementing

PATHH to distribute up to $200 million as authorized by Subtitle B of Title VII of Division N of the Consolidated Appropriations Act, 2021 (CAA; Pub. L. 116–260) to support timber harvesting and timber hauling businesses that have experienced a decrease in their gross revenue of 10 percent or more for the period of January 1, 2020, and December 1, 2020, compared to gross revenue for the period of January 1, 2019 and December 1, 2019. PATHH is intended for timber harvesting and hauling businesses that derive the majority of their income from timber harvesting or hauling activities.

Timber harvesting and hauling businesses are also commonly referred to as loggers and truckers. This document uses the terms timber harvesting and timber hauling businesses for consistency with the CAA. FSA is administering the direct payments under the general supervision and direction of the FSA Administrator, and the United States Forest Service (USFS). USFS will provide technical assistance to FSA, which includes, but is not limited to, sharing expertise on the timber sector, connecting with stakeholders, and providing outreach and training materials.

Definitions

For PATHH, the following definitions apply:

Gross revenue means the business's gross receipts. Gross receipts are the total amounts the timber harvesting business or timber hauling business received from timber harvesting and timber hauling activities, without subtracting any costs or expenses. For PATHH, applicants should not include sale of physical assets, such as machinery or equipment, when calculating gross revenue.

Legal entity means for the purposes of administering PATHH, a timber harvesting business or timber hauling business that is a corporation, joint stock company, association, limited partnership, irrevocable trust, estate, charitable organization, or other similar organization including any such organization participating in a business structure as a general partnership, a joint venture, a grantor of a revocable trust, or as a participant in a similar organization, is considered a legal entity, subject to the payment limitation and payment eligibility requirements described in this NOFA. A business operating as a sole proprietorship is considered a legal entity.

NAICS means the 2017 North American Industry Classification System (NAICS). It is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.

Person means an individual, natural person and does not include a legal entity.

Principal business code means a six-digit number that classifies the main type of product a business sells or service offered. It is based on NAICS codes and is synonymous in this notice with NAICS.

Timber means trees or logs harvested from forest land. It includes trees or logs that have been minimally processed onsite in the forest before transportation from the forest land (for example, wood chips, slash, etc.).

Timber harvesting business means a business, also known as a logging business, with its gross revenue derived from one or more of the following:

- Cutting timber;
- Cutting and transporting timber; or
- Producing wood chips on forest land.

In addition, the business must be classified under NAICS Code 113310 for tax purposes; or as otherwise determined by the Deputy Administrator for Farm Programs.

Timber hauling business means a business, also known as a log hauling business, with its gross revenue derived from transporting products harvested directly from forest land with vehicles registered (under the laws of the state or states in which the vehicle is required to be registered) as highway motor vehicles used in the transportation of timber. The business must also be classified under NAICS Code 484220 or 484230 for tax purposes and have filed IRS Form 2290 for logging vehicles for 2019 and 2020, or otherwise determined by the Deputy Administrator for Farm Programs.

United States means all 50 states of the United States, the District of Columbia, the Commonwealth of Puerto Rico and any other territory or possession of the United States.

Eligibility

To be eligible for a PATHH payment, an applicant must:

- Be in operation as a timber harvesting business or timber hauling business during the periods of:
  - January 1, 2019, through December 1, 2019, and
  - January 1, 2020, through December 1, 2020; [1]
- Have had at least a 10 percent gross revenue loss when comparing the 2020 period with the 2019 period mentioned above;
- Have 50 percent or more of its gross revenue derived from timber harvesting, timber hauling, or both during the periods of:
  - January 1, 2019, through December 1, 2019, and
  - January 1, 2020, through December 1, 2020;
- Meet all of the requirements in this NOFA;
- Be a:
  - Citizen of the United States;
  - Resident alien, which for purposes of this NOFA means ''lawful alien'' as defined in 7 CFR part 1400;
  - Partnership of citizens or resident aliens of the United States;
  - Corporation, limited liability company, or other organizational structure organized under State law and solely owned by U.S. citizens or resident aliens; or
  - Indian Tribe or Tribal organization, as defined in section 4(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304);
- Provide names and taxpayer identification numbers of each person or legal entity that holds an ownership interest in an eligible legal entity in accordance with 7 CFR 1400.107; [2] and
- Comply with the provisions of 7 CFR part 12, ''Highly Erodible Land and Wetland Conservation,'' and the provisions of 7 CFR 718.6, which address ineligibility for benefits for offenses involving controlled substances.

The following types of applicants are ineligible for PATHH:

- Any legal entity that includes a member at any level of ownership in the entity's ownership structure who is not a citizen of the United States or an alien lawfully admitted into the United States for permanent residence under the Immigration and Nationality Act (8 U.S.C. 1101–1778);
- The following types of businesses or operations:
  - Residential or commercial tree care;
  - Landscape services;
  - Trucking businesses that do not transport trees or logs;
  - Timber broker; and
  - United States Federal, State, and local governments.

[1] Applicants must have operated for part of the eligible PATHH period in both 2019 and 2020 to be eligible for PATHH. FSA will adjust the applicant's gross revenue proportionately if the applicant did not operate during the entire PATHH period.

[2] Like all other programs administered by FSA, names and taxpayer identification numbers are required to limit payments to persons and legal entities.

Payment Limitation

A person or legal entity cannot receive payments of more than $125,000 under PATHH. FSA may reduce the maximum payment limitation after all applications are received based on available funding. Like all other programs administered by FSA, payments made to a PATHH applicant that is a Indian Tribe or Tribal organization, as defined in section 4(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), will not be subject to payment limitation.

Application

To apply for PATHH, each eligible timber harvesting business and timber hauling business must complete the form FSA–1118, Pandemic Assistance for Timber Harvesters and Haulers (PATHH) Program Application, which is available at *https://www.farmers.gov/PATHH* and in FSA county offices. A complete form FSA–1118 must be submitted in person, by mail, email, OneSpan,[3] Box,[4] or facsimile to any FSA county office [5] by October 15, 2021.

In addition to the form FSA–1118, an applicant must submit the additional forms discussed below. Failure of an individual, legal entity, or a member(s) of a legal entity to submit the following payment limitation and payment eligibility forms within 60 days from the date of submitting the PATHH application may result in no payment or a reduced payment, as explained in the previous section.

Applicants will be required to complete form AD–2047 Customer Data Worksheet. This form must be filled out for all applicants, as well as members who own a share in any legal entity applicants, who have not previously provided detailed information to USDA that accurately identifies the applicant or member.

To facilitate administration of the payment limitation and eligibility requirements, an applicant that is a legal entity, such as a limited liability company, will be required to complete form CCC–901 Member Information for Legal Entities and provide names and taxpayer identification numbers of all members holding an ownership interest in the legal entity.

A highly erodible land conservation (sometimes referred to elsewhere as HELC) and wetland conservation certification (form AD–1026 Highly Erodible Land Conservation (HELC) and Wetland Conservation (WC) Certification for PATHH applicant and applicable affiliates) will be required for all applicants.

An applicant applying as a timber hauling business must submit a copy of IRS Form 2290 Heavy Highway Vehicle Use Tax Return for logging vehicles for 2019 and 2020 or they will be ineligible for a PATHH payment. For a timber hauling business that only operates on Tribal land, Form 2290 will not be required. The timber hauling business will certify to this on the FSA–1118. Under special circumstances, as determined by FSA, a timber hauling business that does not otherwise use Form 2290 may request an exemption.

If requested by FSA, the applicant must provide additional documentation to verify eligibility of the information included on the application, such as tax records with NAICS 113310 or 484220, as well as evidence that supports the gross revenue the applicant received from timber harvesting or hauling, such as tax returns, payment receipts, and other documentation that is determined acceptable by FSA.

An applicant, whether a person or legal entity, that either fails to timely provide all required documentation or fails to satisfy an eligibility requirement for the PATHH, is not eligible to receive PATHH payments. A PATHH payment to an eligible legal entity applicant whose member(s) either fails to timely submit a separate AD–2047 form or fails to satisfy an eligibility requirement, other than the requirement that the member be a citizen of the United States or an alien lawfully admitted into the United States for permanent residence,[6] will be reduced proportionate to that member's ownership share.

PATHH participants are required to retain documentation in support of their application for 3 years after the date of approval.

Participants receiving PATHH payments or any other person who furnishes such information to USDA must permit authorized representatives of FSA or the Government Accountability Office, during regular business hours, to enter the participant's business and to inspect, examine, and to allow representatives to make copies of books, records, or other items for the purpose of confirming the accuracy of the information provided by the participant.

Payment

For eligible applicants, if gross revenue for the period of January 1, 2020, through December 1, 2020, decreased by at least 10 percent compared to gross revenue for the period of January 1, 2019, through December 1, 2019, the payment amount will be calculated as follows:

- Gross revenue received from January 1, 2019, through December 1, 2019, minus gross revenue received from January 1, 2020, through December 1, 2020;
- Multiplied by 80 percent.

For applicants whose business either originated between January 1, 2019, and December 1, 2019, or dissolved in between January 1, 2020, and December 1, 2020, the applicant must report the amount of time they were in business during the eligible PATHH periods of January 1, 2019, through December 1, 2019, and January 1, 2020, through December 1, 2020, on their application, and FSA will adjust gross revenue proportionally for the purpose of payment calculation. If there was a change in the ownership of an entity in 2019, but the entity's name and business remain the same, the entity is not considered to have originated in 2019. For example, Timber Business A originated on July 17, 2019. It is still in operation today; therefore, it was in operation during PATHH periods January 1, 2020, through December 1, 2020, (336 days) and July 17, 2019, to December 1, 2019 (138 days). The business's gross revenue is $140,000 for 2019, and $200,000 in 2020. Since the number of days the business existed in 2019 is not the same as the number of days it existed in 2020, the business's gross revenue for 2019 will be calculated on a daily basis, and that daily revenue will then be multiplied by the number of days it operated in 2020. This will allow an equitable comparison of the gross revenue for the 2 years to determine the loss. To calculate the

[3] OneSpan is a secure eSignature solution for FSA customers. No software downloads or eAuthentication is required for OneSpan. Applicants interested in eSignature through OneSpan can confirm their identity through two-factor authentication (2FA). For the second factor of authentication, applicants can use a text message with verification code sent to their mobile device or a personalized question and answer. Once identity is confirmed, documents can be reviewed and e-signed through OneSpan via the applicant's personal email address and, once signed, immediately become available to the appropriate FSA county office staff.

[4] Box is a secure, cloud-based site where FSA documents can be managed and shared. Applicants who choose to use Box can create a username and password to access their secure Box account, where documents can be downloaded, printed, manually signed, scanned, uploaded, and shared digitally with FSA county office staff. This service is available to any FSA customer with access to a mobile device or computer with printer connectivity. Box does not require software downloads or an eAuthentication account.

[5] The FSA county office locator can be found at the following site under the ''Find Your Local Service Center'' section: *https://www.farmers.gov/*.

[6] If a member fails to satisfy this eligibility requirement, the applicant is not eligible under the PATHH.

business's gross revenue for 2019, $140,000, will be divided by the number of days its operation existed, 138 days, to get the business's 2019 gross revenue per day. That amount, $1,014.49275 (not rounded), is then multiplied by the number of days the business existed in 2020 if the business existed during the entire application period, 335 days. This amount, $339,855.0724 (not rounded) will then be used as the business's 2019 gross revenue in the PATHH payment calculation. Seasonal timber harvesting and timber hauling business will be considered in operation during the entire PATHH applicable period and their gross revenue will not be prorated.

FSA will issue an initial payment equal to the lesser of:

- The amount calculated above; or
- $2,000.

After the close of the application period, FSA will issue a final payment equal to the amount calculated above minus the amount of the applicant's initial payment. If total calculated payments exceed the total funding available for PATHH, the payment limitation may be adjusted and the final payment amounts will be prorated to stay within the amount of available funding. An initial payment to a recipient will not be recalculated or reduced if the factored payment to that recipient is $2,000 or less.

Miscellaneous Provisions

In the event that a PATHH payment resulted from erroneous information reported by the applicant, the payment will be recalculated, and the applicant must refund any excess payment to FSA, including interest to be calculated from the date of disbursement.

If FSA determines that the applicant intentionally misrepresented their total gross revenue, their application will be disapproved and they must refund to USDA all PATHH payments made to the applicant with interest from the date of disbursement.

If any corrections to the ownership interest in the business result in a lower PATHH payment, the applicant must refund the difference with interest from the date of disbursement.

Any required refunds must be resolved in accordance with debt settlement regulations in 7 CFR part 3.

Equitable relief and finality provisions of 7 CFR 718 subpart D apply to determinations under PATHH, as well as appeal regulations in 7 CFR parts 11 and 780. The determination of matters of general applicability that are not in response to, or result from, an individual set of facts in an individual participant's application for payment are not matters that can be appealed. Such matters of general applicability include, but are not limited to, program definitions, payment limitation, the method of determining gross revenue loss, and the PATHH payment calculation.

A timber hauling business or timber harvesting business may file an application with the FSA county office after the PATHH application deadline, along with a statement as to why the application is being filed after the deadline. In such case the application and statement will be considered a request to waive the application deadline. If funding is available, the Deputy Administrator has the discretion and authority to consider the case and waive or modify application deadlines and other requirements or program provisions not specified in law, in cases where the Deputy Administrator determines it is equitable to do so and where the Deputy Administrator finds that the lateness or failure to meet such other requirements or program provisions do not adversely affect the operation of PATHH. Although applicants have a right to a decision on whether they filed applications by the deadline or not, applicants have no right to a decision in response to a request to waive or modify deadlines or program provisions. The Deputy Administrator's refusal to exercise discretion to consider the request will not be considered an adverse decision and is, by itself, not appealable.

PATHH payments will be made without regard to questions of title under State law and without regard to any claim or lien against the timber harvesting or hauling business. The regulations governing offsets in 7 CFR part 3 do not apply to PATHH payments.

Perjury

In either applying for or participating in PATHH, or both, the applicant is subject to laws against perjury and any penalties and prosecution resulting therefrom, with such laws including but not limited to 18 U.S.C. 1621. If the applicant willfully makes and represents as true any verbal or written declaration, certification, statement, or verification that the applicant knows or believes not to be true, in the course of either applying for or participating in PATHH, or both, then the applicant is guilty of perjury and, except as otherwise provided by law, may be fined, imprisoned for not more than 5 years, or both, regardless of whether the applicant makes such verbal or written declaration, certification, statement, or verification within or without the United States.

Paperwork Reduction Act Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the emergency information collection request has been submitted to the Office of Management and Budget (OMB). OMB approved the 6-month emergency PATHH information collection activity. FSA is providing direct payments to eligible applicants who have suffered a gross revenue loss of at least 10 percent for the period of January 1, 2020, through December 1, 2020, compared to the period of January 1, 2019, through December 1, 2019.

Environmental Review

The environmental impacts have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and the FSA regulation for compliance with NEPA (7 CFR part 799).

As previously stated, PATHH is providing payments to eligible timber harvesting and hauling businesses who have suffered a gross revenue loss of at least 10 percent for the period of January 1, 2020, through December 1, 2020, compared to the period of January 1, 2019, through December 1, 2019. The limited discretionary aspects of PATHH do not have the potential to impact the human environment as they are administrative. Accordingly, these discretionary aspects are covered by the FSA Categorical Exclusions specified in 7 CFR 799.31(b)(6)(iii) that applies to price support programs and § 799.31(b)(6)(vi) that applies to safety net programs.

No Extraordinary Circumstances (§ 799.33) exist. As such, the implementation of PATHH and the participation in PATHH do not constitute major Federal actions that would significantly affect the quality of the human environment, individually or cumulatively. Therefore, FSA will not prepare an environmental assessment or environmental impact statement for this action and this document serves as documentation of the programmatic environmental compliance decision for this federal action.

Federal Assistance Programs

The title and number of the Federal assistance programs, as found in the Catalog of Federal Domestic Assistance, to which this document applies is 10.137—Pandemic Assistance for Timber Harvesters and Haulers Program.

USDA Non-Discrimination Policy

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

Persons with disabilities who require alternative means of communication for program information (for example, braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA TARGET Center at (202) 720–2600 or (844) 433–2774 (toll-free nationwide). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at *https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint* and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410 or email: *OAC@usda.gov.* USDA is an equal opportunity provider, employer, and lender.

Zach Ducheneaux,

Administrator, Farm Service Agency.

[FR Doc. 2021–15683 Filed 7–22–21; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Summer Food Service Program

AGENCY: Food and Nutrition Service (FNS), Agriculture (USDA).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on the Agency's proposed revision to the currently approved information collection for the Summer Food Service Program (SFSP). FNS uses this collection to obtain account and record information from State and program operators that is necessary to effectively manage the SFSP and ensure compliance with statutory and regulatory Program requirements.

DATES: Written comments must be received on or before September 21, 2021.

ADDRESSES: Comments may be sent to Megan Geiger, Community Meals Program Monitoring Branch, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314. Comments may also be submitted via email to *megan.geiger@usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Megan Geiger, Community Meals Program Monitoring Branch, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, at 703–605–3223 or via email to *megan.geiger@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the Agency's functions, including whether the information will have practical utility; (2) the accuracy of the Agency's estimate of the proposed information collection burden, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: 7 CFR part 225, Summer Food Service Program.

OMB Number: 0584–0280.

Expiration Date: December 31, 2022.

Type of Request: Revision of a currently approved collection.

Abstract: The Summer Food Service Program (SFSP) is authorized under section 13 of the Richard B. Russell National School Lunch Act (NSLA) (42 U.S.C. 1761). The Program is directed toward children in low-income areas when school is not in session and is administered by FNS in partnership with State agencies and local program sponsors. Approved sponsors may include public or private non-profit school food authorities (SFAs), public or private non-profit residential summer camps, units of local, municipal, county or State governments, or other private non-profit organizations that develop a special summer program and provide meal service similar to that available to children during the school year under the National School Lunch Program and the School Breakfast Program. Collection of information is required to administer and operate SFSP in accordance with the NSLA.

FNS will seek approval by the Office of Management and Budget (OMB) to revise the reporting burden in the information collection for the SFSP under OMB Control Number 0584–0280 to include two existing monitoring requirements that were omitted in previous ICRs. Under current regulations, sponsors are required to visit each of their sites at least once during the first week of operation under the program (7 CFR 225.15(d)(2)), and to conduct a full review of food service operations at each site within the first four weeks of operation ((7 CFR 225.15(d)(3)). The burden associated with these existing monitoring requirements was overlooked in previous ICRs and has not yet been approved under the Paperwork Reduction Act. This revision corrects these omissions. In addition, FNS is taking this opportunity to correct rounding errors in the total estimated burden hours currently approved for the collection.

FNS estimates that each of the 5,524 sponsors that participate in SFSP (3,314 local and tribal government sponsors, and 2,210 business sponsors) complete, on average, nine first week site visit reports and nine food service reviews annually, for a total of 99,432 responses. In addition, FNS estimates that the average number of burden hours per response is 30 minutes (0.50 hours) for first week site visits, and two hours for

food service reviews, resulting in an estimated total of 124,290 additional burden hours annually (5,524 × 9 × 2.5). As a result of program adjustments for these two monitoring requirements, the reporting burden associated with this collection increases from 328,870 hours and 185,884 responses to 453,160 hours and 285,316 responses. These adjustments do not affect the currently approved recordkeeping and public disclosure burdens.

Furthermore, in preparation for this ICR, FNS discovered erroneous rounding errors in the burden chart submitted as part of the previous renewal request, which resulted in an additional two hours to the total burden estimate for the collection. During that renewal, which was approved by OMB on December 2, 2019, the total public disclosure burden was entered as 1,395 hours when it should have more accurately been rounded to 1,394 hours. In addition, the total burden hours estimate for the collection was rounded up an additional hour when it should have been rounded down. Because of these two rounding errors, current OMB inventory for this collection totals 338,411 hours rather than the more accurate total of 338,409 hours.

As a result of the program adjustments subject to this notice, due to the addition of previously omitted reporting requirements, as well as the administrative adjustment for rounding errors, FNS estimates the revised total burden for the collection to increase by 124,288 hours (124,290 for the two monitoring requirements − 2 to correct rounding errors) and 99,432 responses, to a total of 462,699 hours and 391,795 responses. The adjusted average burden per response and the annual burden hours for reporting, recordkeeping, and public disclosure are explained below and summarized in the charts that follow. The charts reflect the changes in reporting burden at the State/Local/Tribal Government and Business Sponsors levels and the correction of rounding errors in the public disclosure burden. No changes were made in the recordkeeping burden.

Affected Public: State, Local, or Tribal Governments and Businesses or Other For Profit, or Not for Profit. Respondent groups identified include State Agencies and local, tribal, and business sponsors.

Estimated Number of Respondents: 63,942.

Estimated Number of Responses per Respondent: 6.13.

Estimated Total Annual Responses: 391,795.

Estimated Time per Response: 1.18.

Estimated Total Annual Burden: 462,699.

Current OMB Inventory: 338,411.

Difference (Burden Revisions Requested): 124,288.

Refer to the table below for estimated total annual burden for each type of respondent.

Affected public	Est. number of responses	Number of responses per respondent	Total annual responses (records)	Est. total hours per response	Est. total burden
Reporting (addition of previously omitted requirements)					
Requirement/Activity: 225.15(d)(2) Sponsors must conduct a site visit during the first two weeks of operation under the program for new sites, sites with operational problems, and any site where the SA deems a visit is necessary.					
State/Local/Tribal Government Level (sponsors)	3,314	9	29,826	0.50	14,913
Requirement/Activity: 225.15(d)(3) Sponsors must conduct food service reviews for all sites within the first month of starting operations, and thereafter maintain a reasonable level of monitoring.					
State/Local/Tribal Government Level (sponsors)	3,314	9	29,826	2	59,652
State/Local/Tribal Government Level (sponsors) Total	3,314	18	59,652	1.25	74,565
Requirement/Activity: 225.15(d)(2) Sponsors must conduct a site visit during the first two weeks of operation under the program for new sites, sites with operational problems, and any site where the SA deems a visit is necessary.					
Business Sponsors Level	2,210	9	19,890	0.50	9,945
Requirement/Activity: 225.15(d)(3) Sponsors must conduct food service reviews for all sites within the first month of starting operations, and thereafter maintain a reasonable level of monitoring.					
Business Sponsors Level	2,210	9	19,890	2	39,780
Business Sponsors Level Total	2,210	18	39,780	1.25	49,725
Total Change in Reporting Burden	5,524	18	99,432	1.25	124,290
Public Disclosure (correction of rounding errors)					
Requirement/Activity: 225.15(e) Per policy guidance, State agency can issue a media release on behalf of the sponsor.					
State/Local/Tribal Government Level	53	1	53	0.25	13.25
Requirement/Activity: 225.15(e) Each sponsor shall annually announce in the media serving the area from which it draws its attendance the availability of free meals.					
State/Local/Tribal Government Level	3,314	1	3,314	0.25	828.50
State/Local/Tribal Government Level Total	3,367	1	3,367	0.25	841.75
Requirement/Activity: 225.15(e) Each sponsor shall annually announce in the media serving the area from which it draws its attendance the availability of free meals.					

Affected public	Est. number of responses	Number of responses per respondent	Total annual responses (records)	Est. total hours per response	Est. total burden
Business Sponsors Level Total	2,210	1	2,210	0.25	552.50
Estimated Public Disclosure Burden Total	5,577	1	5,577	0.25	1,394.25

Total Burden for SFSP

	Est. number of respondents	Number of responses per respondent	Total annual responses	Est. total hours per response	Est. total burden
Reporting (with changes)	63,942	4.46	285,316	1.59	453,159.55
Recordkeeping (no change)	5,577	18.09	100,902	0.08	8,145.42
Public Disclosure (with changes)	5,577	1	5,577	0.25	1,394.25
Total Burden for SFSP	63,942	6.13	391,795	1.181	462,699.22

Tameka Owens,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2021–15679 Filed 7–22–21; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

Census Bureau

Request for Nominations of Members To Serve on the National Advisory Committee on Racial, Ethnic, and Other Populations

AGENCY: Census Bureau, Commerce.

ACTION: Notice of request for nominations.

SUMMARY: The Director of the Census Bureau (Director) is seeking nominations for the National Advisory Committee on Racial, Ethnic and Other Populations (NAC). The purpose of the NAC is to provide advice to the Director on the full range of economic, housing, demographic, socioeconomic, linguistic, technological, methodological, geographic, behaviorial and operational variables affecting the cost, accuracy and implementation of Census Bureau programs and surveys, including the decennial census. The Director has determined that the work of the NAC is in the public interest and relevant to the duties of the Census Bureau. Therefore, the Director is seeking nominations to fill vacancies on the NAC. Additional information concerning the NAC can be found by visiting the NAC's website at: *https://www.census.gov/about/cac/sac.html.*

DATES: Nominations must be received on or before September 30, 2021. Nominations must contain a completed resume. The Census Bureau will retain nominations received after the deadline for consideration should additional vacancies occur.

ADDRESSES: Please submit nominations via email to the address listed below, *census.national.advisory.committee@census.gov* (subject line 2021 NAC Nominations'').

FOR FURTHER INFORMATION CONTACT: Shana Banks, Chief, Advisory Committee Brach, Office of Program, Performance and Stakeholder Integration (PPSI), Census Bureau, by telephone at 301–763–3815 or by email at *Shana.J.Banks@census.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Federal Advisory Committee Act (FACA), Title 5, United States Code, Appendix 2, Section 10, the Director of the Census Bureau is seeking nominations for the National Advisory Committee on Racial, Ethnic, and Other Populations (NAC). The NAC will operate under the provisions of FACA and will report to the Secretary of the Department of Commerce through the Director of the Census Bureau.

The Census Bureau's National Advisory Committee on Racial, Ethnic, and Other Populations will advise the Director of the Census Bureau on the full range of Census Bureau programs and activities. The Advisory Committee will provide race, ethnic, and other population expertise from the following disciplines: Economic, housing, demographic, socioeconomic, linguistic, technological, methodological, geographic, and behavioral and operational variables affecting the cost, accuracy, and implementation of Census Bureau programs and surveys, including the decennial census.

Objectives and Duties

1. The NAC advises the Director of the Census Bureau (the Director) on the full range of economic, housing, demographic, socioeconomic, linguistic, technological, methodological, geographic, behavioral, and operational variables affecting the cost, accuracy, and implementation of Census Bureau programs and surveys, including the decennial census.

2. The NAC advises the Census Bureau on the data needs of underserved communities and how census data products might address such needs.

3. The NAC provides guidance on census policies, research and methodology, tests, operations, communications/messaging, and other activities to ascertain needs and best practices to improve censuses, surveys, operations, and programs.

4. The NAC reviews and provides formal recommendations and feedback on working papers, reports, and other documents related to the design and implementation of Census Bureau programs and surveys.

5. In providing insight, perspectives, and expertise on the full spectrum of Census Bureau surveys and programs, the NAC examines such areas as hidden households, language barriers, students and youth, aging populations, American Indian and Alaska Native tribal considerations, new immigrant populations, populations affected by natural disasters, highly mobile and migrant populations, complex households, poverty, race/ethnic distribution, privacy and confidentiality, rural populations and businesses, individuals and households with limited access to information and communications technologies, the dynamic nature of new businesses, minority ownership of businesses, as well as other concerns impacting

Census Bureau survey design and implementation.

6. The NAC uses formal advisory committee meetings, webinars, web conferences, working groups, and other methods to accomplish its goals, consistent with the requirements of the FACA. The NAC will consult with regional office staff to help identify regional, local, tribal and grass roots issues, trends and perspectives related to Census Bureau surveys and programs.

7. The NAC functions solely as an advisory body under the FACA.

Membership

1. The NAC consists of up to 32 members who serve at the discretion of the Director. The Census Bureau is seeking eight qualified candidates to be considered for appointment.

2. The NAC aims to have a balanced representation among its members, considering such factors as geography, age, sex, race, ethnicity, technical expertise, community involvement, and knowledge of census programs and/or activities.

3. The NAC aims to include members from diverse backgrounds, including state, local and tribal governments; academia; research, national and community-based organizations; and, the private sector.

4. Members will be selected from the public and private sectors. Members may serve as Special Government Employees (SGEs) or representatives who are selected to represent specific organizations.

5. SGEs and representatives will be selected based on their expertise in or representation of specific areas to include: Diverse populations (including race and ethnic populations); national, state, local, and tribal interest organizations serving hard-to-count populations; researchers; community-based organizations; academia; business interests; marketing and media professionals; researchers; and, members of professional associations. Members will be individually advised of the capacity in which they will serve through their appointment letters.

6. Membership is open to persons who are not seated on other Census Bureau stakeholder entities (*i.e.,* State Data Centers, Census Information Centers, Federal State Cooperative on Populations Estimates Program, other Census Advisory Committees, etc.). People who have already served one full-term on a Census Bureau Advisory Committee may not serve on any other Census Bureau Advisory Committee for three years from the termination of previous service. No employee of the federal government can serve as a member of the NAC.

7. Members will serve for a three-year term. All members will be reevaluated at the conclusion of each term with the prospect of renewal, pending the committee needs. Active attendance and participation in meetings and activities (*e.g.,* conference calls and assignments) will be factors considered when determining term renewal or membership continuance. Members may be appointed for a second three-year term at the discretion of the Director.

8. Members will be selected on a standardized basis, in accordance with applicable Department of Commerce guidance.

Miscellaneous

1. Members of the NAC serve without compensation, but receive reimbursement for committee-related travel and lodging expenses.

2. The NAC meets at least twice a year, budget permitting, but additional meetings may be held as deemed necessary by the Census Bureau Director or Designated Federal Officer. All NAC meetings are open to the public in accordance with the FACA.

Nomination Process

1. Nominations should satisfy the requirements described in the Membership section above.

2. Individuals, groups, and/or organizations may submit nominations on behalf of candidates. A summary of the candidate's qualifications (réesumée or curriculum vitae) must be included along with the nomination letter. Nominees must be able to actively participate in the tasks of the committee, including, but not limited to, regular meeting attendance, committee meeting discussant responsibilities, review of materials, as well as participation in conference calls, webinars, working groups, and/or special committee activities.

3. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse NAC membership.

Ron S. Jarmin, Acting Director, Census Bureau, approved the publication of this Notice in the **Federal Register**.

Dated: July 20, 2021.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–15682 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Commodity Flow Survey (CFS)

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed reinstatement, with change, of the Commodity Flow Survey, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 21, 2021.

ADDRESSES: Interested persons are invited to submit written comments by email to *Thomas.J.Smith@census.gov.* Please reference Commodity Flow Survey in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2021–0017, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Berin Linfors, Branch Chief, at 301–763–5366 or *berin.linfors@census.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Commodity Flow Survey, a component of the 2022 Economic Census, is the only comprehensive and publicly available source of multimodal, system-wide data on the volume and pattern of goods movements in the United States. The Commodity Flow Survey is conducted in partnership with the Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology, U.S. Department of Transportation.

The Commodity Flow Survey data are used by policy makers and transportation planners in various federal, state, and local agencies to assess the demand for transportation facilities and services, energy use, safety risks, and environmental concerns. Additionally, business owners, private researchers, and analysts use the Commodity Flow Survey data for analyzing trends in the movement of goods, mapping spatial patterns of commodity and vehicle flows, forecasting demands for the movement of goods, and determining the needs for associated infrastructure and equipment.

The survey provides data on the movement of commodities in the United States from their origin to destination. The survey produces summary statistics on value, tons, ton-miles and average miles by commodity, industry, and mode of transportation. The Census Bureau will publish these shipment characteristics for the nation, census regions and divisions, states, and CFS defined geographical areas.

Primary strategies for reducing respondent burden in the Commodity Flow Survey include: Employing a stratified random sample of business establishments, requesting data on a limited sample of shipment records from each establishment with the option to provide all shipments in the week, accepting estimates of shipping activity, applying machine learning to code products based on their descriptions, providing electronic reporting and including the option for consolidated reporting of multiple locations through a single login for larger companies.

II. Method of Collection

The Commodity Flow Survey will be conducted on a sample of business establishments classified in mining, manufacturing, wholesale, and select retail and services industries, as defined by the North American Industry Classification System (NAICS). The survey will also cover auxiliary establishments (*i.e.,* warehouses and managing offices) of multi-establishment companies. Each selected establishment will be surveyed four times, once during each calendar quarter of 2022. Quarters one and four will include a supplement with questions on hazardous materials packaging for companies that ship hazardous materials. Each questionnaire will ask the establishment to report data for up to 100 shipments for a predetermined reporting week. These data will include the value, net weight, commodity, and origin and destination of each selected shipment. Survey responses will be collected electronically, and respondents will have the option to provide all shipments for the reporting week instead of sampling shipments.

III. Data

OMB Control Number: 0607–0932.

Form Number(s): CFS 1000 (2022).

Type of Review: Regular submission, Request for a Reinstatement, with Change, of a Previously Approved Collection.

Affected Public: Business and other for-profit, small businesses or organizations.

Estimated Number of Respondents: 160,000.

Estimated Time per Response: 2.5 hours.

Estimated Total Annual Burden Hours: 1,600,000.

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 U.S.C., Sections 8(b), 131 and 193; Title 49 U.S.C., Section 6302.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–15681 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–980]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules From the People's Republic of China: Partial Rescission of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is partially rescinding the administrative review of the countervailing duty order on crystalline silicon photovoltaic cells (solar cells) from the People's Republic of China (China) for the period of review (POR) January 1, 2019, through December 31, 2019.

DATES: Applicable July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Chien-Min Yang, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5484.

SUPPLEMENTARY INFORMATION:

Background

On December 2, 2020, Commerce published a notice of opportunity to request an administrative review of the countervailing duty order on solar cells from China.[1] Pursuant to requests from

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity*

interested parties, on February 4, 2021, Commerce published the notice of initiation of an administrative review with respect to 83 companies, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).[2] Subsequent to the initiation of the administrative review, the petitioner [3] timely withdrew its request for an administrative review of 19 companies on May 5, 2021.[4] Eight [5] of the 19 companies requested their own review of their entries and did not withdraw their requests for review.[6] Thus, Commerce will only be rescinding this review with respect to the 11 companies for which a review request was received and subsequently withdrawn by the party(ies) requesting review.

BYD (Shangluo) Industrial Co., Ltd. (BYD) also withdrew its self-requested review on May 5, 2021.[7] However, the petitioner also requested a review of BYD and has not withdrawn the request; therefore, Commerce will not rescind the review with respect to BYD. There are active review requests on the record for the remaining 72 companies.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws its request within 90 days of the date of publication of the notice of initiation. All requests for an administrative review were withdrawn by the established deadline of May 5, 2021, for the companies listed in the appendix. As a result, Commerce is rescinding this review with respect to these companies, in accordance with 19 CFR 351.213(d)(1). The administrative review will continue with respect to the remaining 72 companies listed in our *Initiation Notice*.[8]

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. For the companies for which this review is rescinded, countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse for consumption, in accordance with 19 CFR 351.212(c)(l)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this rescission notice in the **Federal Register**.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(l) of the Act, and 19 CFR 351.213(d)(4).

Dated: July 19, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Companies Rescinded From Review

1. Anji DaSol Solar Energy Science & Technology Co., Ltd.
2. Jiawei Solarchina (Shenzhen) Co., Ltd.
3. Jiawei Solarchina Co., Ltd.
4. Ningbo Qixin Solar Electrical Appliance Co., Ltd.
5. Shanghai BYD Co., Ltd.
6. Shenzhen Sungold Solar Co., Ltd.
7. Shenzhen Topray Solar Co., Ltd.
8. Taizhou BD Trade Co., Ltd.
9. Wuxi Suntech Power Co., Ltd.
10. Luoyang Suntech Power Co., Ltd.
11. Wuxi Tianran Photovoltaic Co., Ltd.

[FR Doc. 2021–15742 Filed 7–22–21; 8:45 am]

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to Request Administrative Review, 85 FR 77431 (December 2, 2020).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 8166 (February 4, 2021) (*Initiation Notice*).

[3] The petitioner is the American Alliance for Solar Manufacturing.

[4] *See* Petitioner's Letter, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated May 5, 2021.

[5] These eight companies are Canadian Solar International Limited (Canadian Solar), Jinko Solar Co., Ltd., Jinko Solar Import and Export Co., Ltd. (collectively Jinko Solar), Shanghai JA Solar Technology Co., Ltd., JA Solar Technology Yangzhou Co., Ltd. JA Solar Co., Ltd. (a.k.a. JingAo Solar Co., Ltd.) (collectively JA Solar), Risen Energy Co., Ltd. (Risen), and Yingli Energy (China) Co., Ltd.(Yingli).

[6] *See* Canadian Solar's Letter, ''Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the People's Republic of China: Request for Review,'' dated December 29, 2020; *see also* Jinko Solar's Letter, ''GDLSK Respondents Request for Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules (C–570–980)(POR: 01/01/19–12/31/19),'' dated December 31, 2020; JA Solar's Letter, ''Administrative Review of the Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules from the People's Republic of China: Request for Review,'' dated December 29, 2020; Risen's Letter, ''Crystalline Silicon Photovoltaic Cells from the People's Republic of China—Request for Administrative Review,'' dated December 31, 2020; and Yingli's Letter, ''Countervailing Duty Order on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules: Yingli's Request for Administrative Review,'' dated December 22, 2020.

[7] *See* BYD's Letter, ''Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China: Withdrawal of Request for Review—2019 Review Period,'' dated May 5, 2021.

[8] *See Initiation Notice,* 86 FR at 8172–73.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–909]

Certain Steel Nails From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Scope Ruling and Notice of Amended Final Scope Ruling Pursuant to Court Decision

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 12, 2021, the U.S. Court of International Trade (CIT) issued its final judgment in *Midwest Fastener Corp.* v. *United States,* Court No. 17–00231, sustaining the Department of Commerce's (Commerce's) remand redetermination pertaining to a scope ruling in which Commerce found Midwest Fastener Corp. (Midwest)'s strike pin anchors to be outside the scope of the antidumping duty (AD) order on certain steel nails from the People's Republic of China. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's scope ruling, and that Commerce is amending the scope ruling to find that Midwest's strike pin anchors are not covered by the order.

DATES: Applicable July 22, 2021.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2517.

SUPPLEMENTARY INFORMATION:

Background

On August 2, 2017, Commerce found Midwest's strike pin anchors, which consist of four components—a steel pin, a threaded body, a nut, and a flat washer—to be within the scope of the AD order on certain steel nails from the People's Republic of China.[1]

Midwest appealed Commerce's *Final Scope Ruling.* On October 19, 2018, the CIT remanded Commerce's scope ruling to Commerce for further consideration.[2] On April 25, 2019, Commerce issued its First Remand Redetermination, determining that the ''pin'' portion ''of the product is subject to the {*Order*}, while the additional pieces, *i.e.,* the outer-body anchor, hex nut, and washer anchor, would not be subject.'' [3]

On March 4, 2020, the CIT again remanded Commerce's scope determination.[4] Pursuant to the *Second Remand Order,* on June 17, 2020, Commerce issued its Second Remand Redetermination, finding that Midwest's strike pin anchors, in their entirety, are covered by the scope of the *Order.*[5]

On August 28, 2020, the U.S. Court of Appeals for the Federal Circuit (CAFC) issued its final decision in *OMG.*[6] In light of the CAFC's decision, on January 21, 2021, the CIT remanded the *Final Scope Ruling* to Commerce.[7]

In its final remand redetermination, issued in March 2021, Commerce found Midwest's strike pin anchors to be outside the scope of the *Order.*[8] The CIT sustained Commerce's final redetermination.[9]

[1] *See* Memorandum, ''Antidumping and Countervailing Duty Orders on Certain Steel Nails from the People's Republic of China: Final Scope Ruling on Midwest Fastener Strike Pin Anchors,'' dated August 2, 2017 (*Final Scope Ruling*); *see also Notice of Antidumping Duty Order: Certain Steel Nails from the People's Republic of China,* 73 FR 44961 (August 1, 2008) (*Order*).

[2] *See Midwest Fastener Corp.,* v. *United States,* 348 F. Supp. 3d 1297 (CIT October 19, 2018).

[3] *See* Final Results of Redetermination Pursuant to Court Remand (First Remand Redetermination), *Midwest Fastener Corp.,* v. *United States Court,* No. 17–00231, Slip Op. 18–142 (CIT October 19, 2018) (First Remand Redetermination).

[4] *See Midwest Fastener Corp.,* v. *United States,* 435 F. Supp. 3d 1262 (CIT March 4, 2020) (*Second Remand Order*).

[5] *See* Final Results of Redetermination Pursuant to Court Remand, *Midwest Fastener Corp.,* v. *United States,* Court No. 17–00231, Slip Op. 20–28 (CIT March 4, 2020) (Second Remand Redetermination).

[6] *See OMG, Inc.* v. *United States,* 972 F.3d 1358 (Fed. Cir. 2020) (*OMG*).

[7] *See Midwest Fastener Corp.,* v. *United States,* 494 F. Supp. 3d 1335 (CIT January 21, 2021).

[8] *See* Final Results of Redetermination Pursuant to *Midwest Fastener Corp.,* v. *United States,* Court No. 17–00231, Slip Op. 21–07 (CIT January 21, 2021), dated March 23, 2021.

[9] *See Midwest Fastener Corp.,* v. *United States,* Slip Op. 21–86, Court No. 17–00231 (CIT July 12, 2021).

Timken Notice

In its decision in *Timken,*[10] as clarified by *Diamond Sawblades,*[11] the CAFC held that, pursuant to sections 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's July 12, 2021, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Scope Ruling.* Thus, this notice is published in fulfillment of the publication requirements of *Timken.*

Amended Final Scope Ruling

In accordance with the CIT's July 12, 2021, final judgment, Commerce is amending its *Final Scope Ruling* and finds that the scope of the order does not cover the products addressed in the *Final Scope Ruling.*

Liquidation of Suspended Entries

Commerce will instruct U.S. Customs and Border Protection (CBP) that, pending any appeals, Midwest's strike pin anchors will not be subject to a cash deposit requirement.

In the event that the CIT's final judgment is not appealed or is upheld on appeal, Commerce will instruct CBP to liquidate entries of Midwest's strike pin anchors without regard to antidumping duties and to lift suspension of liquidation of such entries.

At this time, Commerce remains enjoined by CIT from liquidating entries included in the scope of the *Order* by the *Final Scope Ruling.* These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) of the Act.

Dated: July 19, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–15741 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–DS–P

[10] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[11] *See Diamond Sawblades Manufacturers Coalition* v. United States, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–867]

Large Power Transformers From the Republic of Korea: Notice of Court Decision Not in Harmony With Final Results, Notice of Amended Final Results of Review; 2015–16

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 9, 2021, the Court of International Trade (CIT) sustained the final results of redetermination pursuant to remand pertaining to the administrative review of the antidumping duty order on large power transformers (LPTs) from the Republic of Korea (Korea) covering the period August 1, 2015, through July 31, 2016. The Department of Commerce (Commerce) is notifying the public that the final judgment is not in harmony with the final results of the administrative review, and that Commerce is amending the final results of review with respect to the weighted-average dumping margin assigned to Hyundai Heavy Industries Co., Ltd., Hyosung Corporation, and the non-examined company ILJIN Electric Co., Ltd.

DATES: Applicable July 19, 2021.

FOR FURTHER INFORMATION CONTACT: John K. Drury, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0195.

SUPPLEMENTARY INFORMATION:

Background

On March 16, 2018, Commerce issued the final results of the administrative review for the period August 1, 2015, through July 31, 2016.[1] In the *Final Results,* Commerce determined a weighted-average dumping margin for the two mandatory respondents, Hyundai Heavy Industries Co., Ltd. (Hyundai) and Hyosung Corporation (Hyosung), based on total facts available with an adverse inference, of 60.81 percent. Further, Commerce determined the weighted-average dumping margin for the three companies that were under review but not selected for individual examination, ILJIN, ILJIN Electric Co., Ltd. (ILJIN Electric), and LSIS Co., Ltd.

[1] *See Large Power Transformers from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2015–2016,* 83 FR 11679 (March 16, 2018) (*Final Results*), and accompanying Issues and Decision Memorandum.

(LSIS), based on the rates determined for the mandatory respondents.

On August 5, 2019, the CIT remanded various aspects of the *Final Results* to Commerce.[2] Specifically, the CIT directed Commerce to further explain or reconsider its reliance on total facts available with adverse inferences for both Hyundai and Hyosung. For Hyundai, the Court directed Commerce to further explain or reconsider its reliance on total facts available with adverse inferences with respect to Hyundai's failure to: (1) Provide information on accessories; (2) report home market gross unit prices properly; and (3) disclose an affiliated sales agent. For Hyosung, the Court directed Commerce to further explain or reconsider its reliance on total facts available with adverse inferences with respect to Hyosung's failure to: (1) Report service-related revenues contained on order acknowledgement forms (OAFs); (2) report certain discounts and rebates; and (3) explain the use of one invoice for multiple sales across multiple administrative reviews.

Pursuant to the *First Remand Order,* Commerce reconsidered and further explained its finding regarding Hyundai's failure to: (1) Provide information regarding accessories; (2) report home market gross unit prices properly; and (3) disclose an affiliated sales agent. Commerce also reconsidered and further explained its findings regarding Hyosung's failure to: (1) Report service-related revenues recorded on OAFs; (2) report certain discounts and rebates; and (3) explain the use of one invoice for multiple sales across multiple administrative reviews.[3] With respect to Hyosung, Commerce determined that the issues related to service-related revenues recorded on OAFs and the use of one invoice for multiple sales across multiple reviews were no longer a basis for Commerce's application of total facts available with adverse inferences but that the failure to report certain discounts and rebates continued to constitute a basis for Commerce's application of total facts available with adverse inferences. For Hyundai, Commerce found that Hyundai's reporting with respect to accessories was not a basis for Commerce's application of total facts available with adverse inferences, but continued to find that the application of total facts available with adverse inferences was warranted due to the understatement of home market prices and inconsistent treatment of merchandise under consideration.[4]

On November 18, 2020, the CIT remanded Commerce's Final First Results of Redetermination with respect to the application of total adverse facts available for both Hyundai and Hyosung, finding that Commerce's redeterminations were not supported by substantial evidence.[5] Pursuant to the *Second Remand Order,* Commerce reconsidered its reliance on total facts available with adverse inferences for both Hyundai and Hyosung. Commerce determined that the application of partial facts available with no adverse inferences was warranted with respect to both Hyundai and Hyosung.[6] Commerce calculated a weighted-average dumping margin of zero percent for both Hyundai and Hyosung.[7] Commerce also applied an average of these two rates, *i.e.,* zero percent, to ILJIN Electric, which was not selected for individual examination during the period of review and which was party to this litigation.[8]

On July 9, 2021, the CIT sustained Commerce's Final Second Results of Redetermination.[9]

Timken Notice

In its decision in *Timken,*[10] as clarified by *Diamond Sawblades,*[11] the United States Court of Appeals for the Federal Circuit held that, pursuant to sections 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's July 9, 2021, judgment sustaining Commerce's Final Second Results of Redetermination constitutes a final decision of the CIT that is not in harmony with the *Final Results.* This notice is published in fulfillment of the publication requirements of *Timken.* Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise at issue pending expiration of the period to appeal or, if appealed, pending a final and conclusive court decision.

Amended Final Results

Because there is now a final court decision, Commerce is amending the *Final Results* with respect to the weighted-average dumping margin calculated for Hyundai, Hyosung and ILJIN Electric. Based on the Final Results of Second Redetermination, as affirmed by the CIT, the revised weighted-average dumping margin for Hyundai, Hyosung, and ILJIN Electric, from August 1, 2015, through July 31, 2016, are as follows:

Producer or exporter	Weighted-average dumping margin (percent)
Hyundai Heavy Industries Co., Ltd	0.00
Hyosung Corporation	0.00
ILJIN Electric Co., Ltd	0.00

In the event that the CIT's final judgement is not appealed or, if appealed, is upheld by a final and conclusive court decision, Commerce will instruct U.S. Customs and Border Protection to assess antidumping duties on unliquidated entries of subject merchandise based on the weighted-average dumping margins listed above for the Amended Final Results.

Cash Deposit Requirements

Since the *Final Results,* Commerce has established new cash deposit rates for Hyundai, Hyosung, and ILJIN Electric.[12] Therefore, this Final Results of Second Redetermination, as affirmed by the CIT, and as published in this notice, does not prospectively change the existing cash deposit rates for Hyundai, Hyosung, and ILJIN Electric.

[2] *See Hyundai Heavy Industries, Co. Ltd. and Hyosung Corporation, Iljin Electric Co., Ltd.* v. *United States and ABB Inc.,* Consol. Court No. 18–00066, Slip Op. 19–105 (CIT August 5, 2019) (*First Remand Order*).

[3] *See* Memorandum, ''Final Results of Redetermination Pursuant to Court Remand *Hyundai Heavy Industries, Co. Ltd. and Hyosung Corporation, Iljin Electric Co., Ltd.* v. *United States and ABB Inc.,* Consol. Court No. 18–00066, Slip Op. 19–105 (CIT August 5, 2019),'' dated December 19, 2019, and available at *https://enforcement.trade.gov/remands/19-105.pdf* .

[4] *Id.*

[5] *See Hyundai Heavy Industries, Co. Ltd. and Hyosung Corporation and Iljin Electric Co., Ltd.* v. *United States and ABB Enterprise Software Inc.,* Consol. Court No. 18–00066, Slip Op. 20–165 (CIT November 18, 2020) (*Second Remand Order*).

[6] *See* Memorandum, ''Final Results of Redetermination Pursuant to Court Remand: *Hyundai Heavy Industries, Co. Ltd. and Hyosung Corporation, Iljin Electric Co., Ltd.* v. *United States and ABB Inc.,* Court No. 18–00066, Slip Op. 20–165 (CIT November 18, 2020),'' dated April 5, 2021, and available at *https://enforcement.trade.gov/remands/20-165.pdf* (Final Results of Second Redetermination).

[7] *Id.*

[8] *Id.*

[9] *See Hyundai Heavy Industries, Co. Ltd. and Hyosung Corporation and Iljin Electric Co., Ltd.* v. *United States and ABB Enterprise Software Inc.,* Consol. Court No. 18–00066, Slip Op. 21–84 (CIT July 9, 2021).

[10] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), at 341.

[11] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[12] *See, e.g., Large Power Transformers from the Republic of Korea: Final Results of Antidumping Duty Administrative Duty Administrative Review; 2016–2017,* 84 FR 16461 (April 19, 2019).

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: July 19, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–15743 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–025; C–533–862]

Polyethylene Terephthalate Resin From the People's Republic of China and India: Final Results of the Expedited First Sunset Reviews of the Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these expedited sunset reviews, the Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) orders on polyethylene terephthalate (PET) resin from the People's Republic of China (China) and India would be likely to lead to continuation or recurrence of countervailable subsidies at the levels as indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Joshua A. DeMoss, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3362.

SUPPLEMENTARY INFORMATION:

Background

On May 6, 2016, Commerce published the CVD orders on PET resin from China and India in the **Federal Register**.[1] On March 31, 2021, Commerce published the notice of initiation of the first sunset reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] Commerce received a notice of intent to participate from DAK Americas, LLC, Indorama Ventures USA Inc., and Nan Ya Plastics Corporation, America (collectively, domestic interested parties) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] Each claimed interested party status under section 771(9)(C) of the Act as domestic producers engaged in the production of PET resin in the United States.

On April 30, 2021, Commerce received a substantive response from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] On May 3, 2021, two respondent interested parties, CG Roxane, LLC (CG Roxane) and Niagara Bottling, LLC (Niagara), filed substantive responses pursuant to 19 CFR 351.218(d)(3), to the record of the China sunset review.[5] However, for the substantive responses of respondent interested parties to be considered adequate under this regulation, the respondents must account for, on average, more than 50 percent (volume or value) of total exports during the five-year period preceding the year of publication of the initiation notice, pursuant to 19 CFR 351.218(e)(1)(ii)(A). CG Roxane and Niagara failed to demonstrate this. We did not receive a substantive response from any other interested party in these proceedings.

On May 21, 2021, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[6] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted expedited (120-day) sunset reviews of these *Orders.*

Scope of the Orders

The merchandise covered by these orders is polyethylene terephthalate (PET) resin having an intrinsic viscosity of at least 0.70, but not more than 0.88, deciliters per gram. The scope includes blends of virgin PET resin and recycled PET resin containing 50 percent or more virgin PET resin content by weight, provided such blends meet the intrinsic viscosity requirements above. The scope includes all PET resin meeting the above specifications regardless of additives introduced in the manufacturing process. The merchandise subject to these orders is properly classified under subheading 3907.60.00.30 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise covered by these orders is dispositive.

Analysis of Comments Received

All issues raised in these sunset reviews are addressed in the Issues and Decision Memorandum, including the likelihood of continuation or recurrence of countervailable subsidies and the net countervailable subsidy likely to prevail if the *Orders* were revoked.[7] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/index.html.* A list of the issues discussed in the decision memorandum is attached at the appendix to this notice.

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the *Orders* would be likely to lead to continuation or recurrence of countervailable subsidies at the following rates:

[1] *See Certain Polyethylene Terephthalate Resin from India and the People's Republic of China: Countervailing Duty Order (India) and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order (People's Republic of China),* 81 FR 27977 (May 6, 2016) (*Orders*).

[2] *See Initiation of Five-Year (Sunset) Review,* 86 FR 16701 (March 31, 2021).

[3] *See* Domestic Interested Parties' Letters, ''Five-Year (Sunset) Review of the Countervailing Duty Order on Certain Polyethylene Terephthalate Resin from the People's Republic of China—Domestic Interested Parties' Notice of Intent to Participate,'' dated April 15, 2021; and ''Five-Year (Sunset) Review of the Countervailing Duty Order on Certain Polyethylene Terephthalate Resin from India—Domestic Interested Parties' Notice of Intent to Participate,'' dated April 15, 2021.

[4] *See* Domestic Interested Parties' Letters, ''Five-Year (Sunset) Review of the Countervailing Duty Order on Certain Polyethylene Terephthalate Resin from the People's Republic of China—Domestic Interested Parties' Substantive Response to Notice of Initiation,' dated April 30, 2021 (China Substantive Response); and ''Five-Year (Sunset) Review of the Countervailing Duty Order on Certain Polyethylene Terephthalate Resin from India—Domestic Interested Parties' Substantive Response to Notice of Initiation,'' dated April 30, 2021 (India Substantive Response).

[5] *See* CG Roxane's Letter, ''Sunset Review of Polyethylene Terephthalate Resin from China and Oman: Response to Notice of Institution,'' dated May 3, 2021; and Niagara's Letter, ''Sunset Review of Polyethylene Terephthalate Resin from China: Response to Notice of Institution,'' dated May 3, 2021.

[6] *See* Commerce's Letter, ''Sunset Review for April 2021,'' dated May 21, 2021.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Expedited First Sunset Review of the Countervailing Duty Orders of Polyethylene Terephthalate Resin from the People's Republic of China and India,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Manufacturer/producer/exporter	Net countervailable subsidy rate (percent)
PET Resin From China	
Xingyu	7.53
Dragon Group	47.56
All Others	27.55
PET Resin From India	
Dhunseri	5.12
JBF Industries Limited	153.80
All Others	5.12

Administrative Protective Order

This notice serves as the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act.

Dated: July 16, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Orders
IV. History of the Orders
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Rates Likely to Prevail
3. Nature of the Subsidies
VII. Final Results of Review
VIII. Recommendation

[FR Doc. 2021–15662 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–879]

Methionine From Japan: Final Affirmative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of methionine from Japan are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation July 1, 2019, through June 30, 2020.

DATES: Applicable July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Robert Scully, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0572.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2021, Commerce published in the **Federal Register** the preliminary affirmative determination in the LTFV investigation of methionine from Japan, in which we also postponed the final determination until July 19, 2021.[1] We invited interested parties to comment on the *Preliminary Determination.* A summary of the events that occurred since Commerce published the *Preliminary Determination* may be found in the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is methionine from Japan. For a complete description of the scope of this investigation, *see* Appendix I.

Analysis of Comments Received

All the issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.*

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[3]

Changes Since the Preliminary Determination

Based on our analysis of the comments received, we have made certain changes to the margin calculations for Sumitomo Chemical Company, Ltd. (Sumitomo Chemical). For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Sumitomo Chemical. Therefore, the only rate which is not zero, *de minimis,* or determined entirely under section 776 of the Act is the rate calculated for Sumitomo Chemical. Consequently, the rate calculated for Sumitomo Chemical is also assigned as the rate for all other producers and exporters.

[1] *See Methionine from Japan: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances and Postponement of Final Determination and Extension of Provisional Measures,* 86 FR 12625 (March 4, 2021) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Methionine from Japan,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Commerce's Letter, ''Request for Documentation,'' dated March 17, 2021; *see also* Sumitomo Chemical's Letter, ''Methionine from Japan: Resubmission of March 25, 2021 Verification Questionnaire Response,'' dated April 6, 2021.

Final Negative Determination of Critical Circumstances

Commerce preliminarily determined that critical circumstances exist for Sumitomo Chemicals and with respect to all other producers/exporters.[4] Parties submitted comments regarding our preliminary critical circumstances determination and we have modified our critical circumstances finding for Sumitomo Chemicals and all other producers/exporters for this final determination. Thus, in accordance with section 735(a)(3) of the Act and 19 CFR 351.206, Commerce finds that critical circumstances do not exist for Sumitomo Chemicals or for all other producers/exporters. For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* the Issues and Decision Memorandum.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Sumitomo Chemical Company, Ltd	76.50
All Others	76.50

Disclosure

We intend to disclose the calculations performed in this final determination within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend the liquidation of all appropriate entries of subject merchandise, as described in Appendix I of this notice, entered, or withdrawn from warehouse, for consumption on or after March 4, 2021, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), where appropriate, we will instruct CBP to require a cash deposit for such entries of merchandise equal to the estimated weighted-average dumping margin or estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin. These suspension of liquidation instructions will remain in effect until further notice.

Further, because our final critical circumstances determination is negative, in accordance with section 735(c)(3) of the Act, we will instruct CBP to terminate the retroactive suspension of liquidation ordered at the *Preliminary Determination* for Sumitomo Chemicals and all other producers/exporters and to refund any cash deposits required with respect to entries of subject merchandise covered by the retroactive suspension of liquidation.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of methionine no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding Administrative Protective Orders

This notice will serve as a final reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: July 19, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is methionine and dl-Hydroxy analogue of dl-methionine, also known as 2-Hydroxy 4-(Methylthio) Butanoic acid (HMTBa), regardless of purity, particle size, grade, or physical form. Methionine has the chemical formula $C_5H_{11}NO_2S$, liquid HMTBa has the chemical formula $C_5H_{10}O_3S$, and dry HMTBa has the chemical formula $(C_5H_9O_3S)_2Ca$.

Subject merchandise also includes methionine processed in a third country including, but not limited to, refining, converting from liquid to dry or dry to liquid form, or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope methionine or dl-Hydroxy analogue of dl-methionine.

The scope also includes methionine that is commingled (*i.e.,* mixed or combined) with methionine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

Excluded from this investigation is United States Pharmacopoeia (USP) grade methionine. In order to qualify for this exclusion, USP grade methionine must meet or exceed all of the chemical, purity, performance, and labeling requirements of the United States Pharmacopeia and the National Formulary for USP grade methionine.

Methionine is currently classified under subheadings 2930.40.00.00 and 2930.90.46.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Methionine has the Chemical Abstracts Service (CAS) registry numbers 583–91–5, 4857–44–7, 59–51–8 and 922–50–9. While the HTSUS subheadings and CAS registry number are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[4] *See* Preliminary Decision Memorandum at 4–7.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Changes Since the *Preliminary Determination*
IV. Final Negative Determination of Critical Circumstances
V. Discussion of the Issues
Comment 1: Research and Development (R&D) Expenses
Comment 2: Offset to the General & Administrative (G&A) Ratio
Comment 3: ''Other'' Financial Expenses
Comment 4: Shutdown Adjustment
Comment 5: Startup Adjustment
Comment 6: Packaging Materials/Product Characteristics
Comment 7: Critical Circumstances
VI. Recommendation

[FR Doc. 2021–15755 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–822]

Methionine From Spain: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of methionine from Spain are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation July 1, 2019, through June 30, 2020. Further, Commerce determines that critical circumstances exist for the sole mandatory respondent Adisseo España S.A. (Adisseo España) and for all other producers and exporters.

DATES: Applicable July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Elizabeth Bremer, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4987.

SUPPLEMENTARY INFORMATION:

Background

On March 4, 2021, Commerce published in the **Federal Register** the preliminary affirmative determination in the LTFV investigation of methionine from Spain, in which we also postponed the final determination until July 19, 2021.[1] Commerce invited interested parties to comment on the *Preliminary Determination.* A summary of the events that occurred since Commerce published the *Preliminary Determination,* may be found in the Issues and Decision Memorandum.[2]

Scope of the Investigation

The product covered by this investigation is methionine from Spain. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

During the course of this investigation, Commerce received no scope comments from interested parties. Therefore, Commerce is not modifying the scope language as it appeared in the *Preliminary Determination. See* Appendix I for the final scope of the investigation.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn.*

Verification

Commerce was unable to conduct on-site verification of the information relied upon in making its final determination in this investigation. However, we took additional steps in lieu of an on-site verification to verify the information relied upon in making this final determination, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act).[3]

Changes Since Preliminary Determination

Based on our analysis of the comments received and our findings related to our request for information in lieu of verification, we made certain changes to the margin calculations with respect to Adisseo España, the sole mandatory respondent in this investigation. In light of these changes to the margin calculations and the resulting revised estimated weighted average dumping margin for Adisseo España, we have also revised the all-others rate. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Affirmative Determination of Critical Circumstances

In accordance with section 733(e) of the Act and 19 CFR 351.206, Commerce preliminarily determined that critical circumstances did not exist for Adisseo España or for all others.[4] Commerce did not receive any comments in response to its preliminary determination with respect to critical circumstances. However, for this final determination, Commerce determines that critical circumstances exist, within the meaning of section 735(a)(3) of the Act and 19 CFR 351.206, for imports of methionine from Spain exported and/or produced by Adisseo España and imports of methionine from Spain produced and/or exported by all other companies. For a full description of methodology and results of Commerce's final affirmative critical circumstances analyses, *see* Issues and Decision Memorandum.

Product Characteristics

Commerce preliminary identified three criteria for the physical characteristics of the subject merchandise: (1) Type; (2) form; and (3) concentration level of methionine content.[5] For this final determination, we made no changes to physical characteristics in our analysis. However, because Commerce made a change with respect to packaging characteristics in

[1] *See Methionine from Spain: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Negative Determination of Critical Circumstances, Postponement of Final Determination and Extension of Provisional Measures,* 86 FR 12614 (March 4, 2021) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Decision Memorandum for the Final Affirmative Determination in the Less-Than-Fair-Value Investigation of Methionine from Spain,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Commerce's Letter, ''Remote Verification Questionnaire for Adisseo España,'' dated March 29, 2021; *see also* Adisseo España's Letter, ''Antidumping Investigation of Methionine from Spain: Response to the Department's Remote Verification Questionnaire,'' dated April 6, 2021.

[4] For a full description of the methodology and results of Commerce's critical circumstances analysis, *see* Preliminary Determination Memorandum at 4.

[5] *See* Commerce's Letter, ''Product Characteristics for Use in Sections B and C Questionnaire Responses of Methionine from Spain,'' dated September 25, 2020*; see also Preliminary Determination* PDM at 12.

the final determination of *Methionine from Japan,*[6] if Commerce were to issue an antidumping duty order in this case, we expect to reexamine this issue during the first administrative review conducted in this proceeding.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated weighted-average dumping margin for all other producers and exporters not individually investigated shall be equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated excluding rates that are zero, *de minimis,* or determined entirely under section 776 of the Act. Pursuant to section 735(c)(5)(B) of the Act, if the estimated weighted-average dumping margins established for all exporters and producers individually examined are zero, *de minimis* or determined based entirely on facts otherwise available, Commerce may use any reasonable method to establish the estimated weighted-average dumping margin for all other producers or exporters.

Commerce calculated an individual estimated weighted-average dumping margin for the sole mandatory respondent, Adisseo España. Therefore, for the purposes of determining the all-others rate, and pursuant to section 735(c)(5)(A) of the Act, we are using the dumping margin calculated for Adisseo España, which is not zero, *de minimis,* or determined entirely under section 776 of the Act. For a full description of the methodology underlying Commerce's analysis, *see* the Issues and Decision Memorandum.

Final Determination

Pursuant to section 735 of the Act, the final estimated weighted-average dumping margins are as follows:

Exporter and/or producer	Estimated weighted-average dumping margin (percent)
Adisseo España S.A.	37.53
All Others	37.53

Disclosure

We intend to disclose the calculations performed in this final determination within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of methionine from Spain, as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after March 4, 2021, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Section 735(c)(4) of the Act provides that if there is an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the later of: (a) The date which is 90 days before the date on which the suspension of liquidation was first ordered; or (b) the date on which notice of initiation of the investigation was published. As noted above, Commerce finds that critical circumstances exist for imports of subject merchandise produced and/or exported by Adisseo España and by all other producers and exporters. Therefore, in accordance with section 735(c)(4) of the Act, suspension of liquidation shall continue to apply to unliquidated entries of subject merchandise produced and/or exported by Adisseo España and by all other producers and exporters that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the date of publication of the *Preliminary Determination* in the **Federal Register**.

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), we will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondent listed above will be equal to the company-specific estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of this final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of methionine from Spain no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, all cash deposits posted will be refunded, and suspension of liquidation will be lifted. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding Administrative Protective Orders

This notice will serve as a final reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: July 19, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is methionine and dl-Hydroxy analogue of dl-methionine, also known as 2-

[6] *See Methionine from Japan: Final Affirmative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances* (*Methionine from Japan*), and the accompanying Issues and Decision Memorandum at Comment 6.

Hydroxy 4-(Methylthio) Butanoic acid (HMTBa), regardless of purity, particle size, grade, or physical form. Methionine has the chemical formula $C_5H_{11}NO_2S$, liquid HMTBa has the chemical formula $C_5H_{10}O_3S$, and dry HMTBa has the chemical formula $(C_5H_9O_3S)_2Ca$.

Subject merchandise also includes methionine processed in a third country including, but not limited to, refining, converting from liquid to dry or dry to liquid form, or any other processing that would not otherwise remove the merchandise from the scope of this investigation if performed in the country of manufacture of the in-scope methionine or dl-Hydroxy analogue of dl-methionine.

The scope also includes methionine that is commingled (*i.e.,* mixed or combined) with methionine from sources not subject to this investigation. Only the subject component of such commingled products is covered by the scope of this investigation.

Excluded from this investigation is United States Pharmacopoeia (USP) grade methionine. In order to qualify for this exclusion, USP grade methionine must meet or exceed all of the chemical, purity, performance, and labeling requirements of the United States Pharmacopeia and the National Formulary for USP grade methionine.

Methionine is currently classified under subheadings 2930.40.00.00 and 2930.90.46.00 of the Harmonized Tariff Schedule of the United States (HTSUS). Methionine has the Chemical Abstracts Service (CAS) registry numbers 583–91–5, 4857–44–7, 59–51–8 and 922–50–9. While the HTSUS subheadings and CAS registry number are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Sections in the Issues and Decision Memorandum

I. Summary
II. Background
III. Changes Since the *Preliminary Determination*
IV. Final Affirmative Determination of Critical Circumstances
V. Discussion of the Issues:
  a. Comment 1: Whether To Grant a Constructed Export Price Offset
  b. Comment 2: Whether Certain Sales Are Outside the Normal Course of Trade
  c. Comment 3: Whether To Recalculate Indirect Selling Expenses (ISE)
  d. Comment 4: Whether To Apply Adverse Facts Available (AFA) on Certain U.S. Sales Fields
VI. Recommendation

[FR Doc. 2021–15753 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB258]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Mackerel, Squid, and Butterfish (MSB) Committee and MSB Advisory Panel will hold a joint public meeting.

DATES: The meeting will be held on Friday, August 6, 2021, from 9 a.m. to 2 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar. Webinar connection, agenda items, and any additional information will be available at *www.mafmc.org/council-events.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for the MSB Committee and MSB Advisory Panel to provide recommendations regarding Atlantic mackerel, potentially including: 2021/22 emergency action, future specifications, and/or rebuilding plan modifications and options.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Collins at the Council Office, (302) 526–5253, at least 5 days prior to the meeting date.

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

Dated: July 20, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–15714 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB261]

Caribbean Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Caribbean Fishery Management Council (CFMC) will hold the 175th public meeting (virtual) to address the items contained in the tentative agenda included in the **SUPPLEMENTARY INFORMATION**.

DATES: The 175th CFMC public meeting (virtual) will be held on August 11, 2021, from 9 a.m. to 5 p.m. The meeting will be at AST (U.S. Caribbean time, presently same as EST).

ADDRESSES: You may join the 175th CFMC public meeting (virtual) via Zoom, from a computer, tablet or smartphone by entering the following address:

Join Zoom Meeting

https://us02web.zoom.us/j/83060685915?pwd=VmVsc1orSUtKck8xYk1XOXNDY1ErZz09
Meeting ID: 830 6068 5915
Passcode: 995658

One Tap Mobile

+17879451488,,83060685915#,,,,,,0#,,995658# Puerto Rico
+17879667727,,83060685915#,,,,,,0#,,995658# Puerto Rico

Dial by Your Location

+1 787 945 1488 Puerto Rico
+1 787 966 7727 Puerto Rico
+1 939 945 0244 Puerto Rico
Meeting ID: 830 6068 5915
Passcode: 995658

In case there are problems and we cannot reconnect via Zoom, the meeting will continue using GoToMeeting.

You can join the meeting from your computer, tablet or smartphone at *https://global.gotomeeting.com/join/971749317.* You can also dial in using your phone. United States: +1 (408) 650–3123 Access Code: 971–749–317.

FOR FURTHER INFORMATION CONTACT: Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918–1903, telephone: (787) 398–3717.

SUPPLEMENTARY INFORMATION: The following items included in the tentative agenda will be discussed:

—Call to Order
—New Members Oath
—Roll Call
—Election of Officers
—Adoption of Agenda
—Consideration of 174th Council Meeting Verbatim Transcriptions
—Executive Director's Report

10 a.m.–10:30 a.m.

—SSC Report—Dr. Richard Appeldoorn
—SEFSC Update

10:30 a.m.–12:30 p.m.

—Island Based Fishery Management Plans (IBFMPs) Status Update
—Generic Amendment to the Fishery Management Plans for Puerto Rico, St. Thomas and St. John, and St. Croix: Modification to the Buoy Gear Definition: Potential Final Action to Submit to the Secretary of Commerce—María López-Mercer, SERO/NOAA Fisheries

Comment Period

—Final Action to Submit the Generic Framework Amendment to the Puerto Rico, St. Thomas and St. John, and St. Croix Fishery Management Plans: Spiny Lobster Management Reference Points to the Secretary of Commerce—Sarah Stephenson, SERO/NOAA Fisheries

Comment Period

12:30 p.m.–1:30 p.m.

—Lunch

1:30 p.m.–2 p.m.

—SEAMAP-Caribbean Gold Copy—J.J. Cruz Motta

2 p.m.–2:30 p.m.

— Outreach and Education Report—Alida Ortiz

2:30 p.m.–3 p.m.

—Enforcement Issues:
—Puerto Rico-DNER
—USVI–DPNR
—U.S. Coast Guard
—NMFS/NOAA

3 p.m.–5 p.m.

—Exempted Fishing Permit (EFP) Update—Sarah Stephenson, SERO/NOAA Fisheries
—5-Minutes Public Comment Period
—Other Business
—Next Meeting

Note (1): Other than starting time and dates of the meetings, the established times for addressing items on the agenda may be adjusted as necessary to accommodate the timely completion of discussion relevant to the agenda items. To further accommodate discussion and completion of all items on the agenda, the meeting may be extended from, or completed prior to the date established in this notice. Changes in the agenda will be posted to the CFMC website, Facebook, Twitter and Instagram as practicable.

Note (2): Financial disclosure forms are available for inspection at this meeting, as per 50 CFR part 601.

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on August 11, 2021, at 9 a.m. AST, and will end on August 11, 2021, at 5 p.m. AST. Other than the start time on the first day of the meeting, interested parties should be aware that discussions may start earlier or later than indicated in the agenda, at the discretion of the Chair.

Special Accommodations

Simultaneous interpretation will be provided.

For simultaneous interpretation English-Spanish-English follow your Zoom screen instructions. You will be asked which language you prefer when you join the meeting.

For any additional information on this public virtual meeting, please contact Diana Martino, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918–1903, telephone: (787) 226–8849.

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

Dated: July 20, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–15708 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; External Needs Assessment for NOAA Education Products and Programs

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 21, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0784 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Bruce Moravchik, National Ocean Service (NOS), 1305 East West Hwy., Bldg. SSMC4, Silver Springs, MD 20910–3278, (240) 533–0874, *bruce.moravchik@noaa.gov* or Shannon Ricles, NOS, Monitor National Marine Sanctuary, 100 Museum Dr., Newport News, VA 23602 (757) 591–7328, *shannon.ricles@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for revision and extension of a currently approved information collection. The National Ocean Service (NOS) on behalf of the NOAA's Education Council is revising and extending a voluntary multi-question survey used to assess the needs of educators pertaining to the development of future NOAA multimedia products and programs. In developing multimedia materials that convey NOAA's science, service, and stewardship, the Agency must ensure that these resources are of the highest quality and meet the needs of formal and informal educators across the United States. To achieve this goal, it is necessary to conduct surveys identifying the types of educational programs and products that are of the highest interest and greatest need by formal and informal educators. By surveying external educators to gather this information, budget expenditures will be used optimally to develop appropriate products and programs most desired by educators to support and enhance Ocean and Earth science,

in addition to other related STEM education subjects throughout our nation. NOAA will use the data to plan, design, and create multimedia products and programs.

The proposed revisions would expand the level of detail in the currently approved information collection. As a result of the Covid–19 pandemic, learning and teaching have changed. The proposed revisions would expound upon previously collected data, giving a better indication of educators' needs regarding multimedia products and programs in their teaching as well as the educator's professional development.

II. Method of Collection

The voluntary needs assessment mechanism will be distributed via email with a link to a Google form to external educators subscribed to NOAA education programs as well as their partners' email distribution lists. The voluntary needs assessment mechanism will also be distributed in person (paper and electronically) at education conferences, workshops, and other venues hosting educators.

III. Data

OMB Control Number: 0648–0784.
Form Number(s): None.
Type of Review: Regular submission [revision and extension of a currently approved collection].
Affected Public: Individuals or households and business or other for-profit organizations.
Estimated Number of Respondents: 1,200 annually.
Estimated Time per Response: Five minutes per survey.
Estimated Total Annual Burden Hours: 100.
Estimated Total Annual Cost to Public: $0.
Respondent's Obligation: Voluntary.
Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act SEC. 315(c).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this information collection. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–15706 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB245]

14th Scientific Advisory Subcommittee to the General Advisory Committee and 29th General Advisory Committee to the U.S. Section to the Inter-American Tropical Tuna Commission; Meeting Announcement

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

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a combined public meeting of the 14th Scientific Advisory Subcommittee (SAS) to the General Advisory Committee (GAC), and the 29th GAC to the U.S. Section to the Inter-American Tropical Tuna Commission (IATTC). This meeting will be held virtually on Friday, July 23, 2021, via webinar, and is the second combined virtual meetings of the SAS and GAC in 2021. The meeting topics are described under the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The virtual meeting of the SAS and GAC will be held on Friday, July 23, 2021, from 9 a.m. to 1 p.m. PDT (or until business is concluded).

ADDRESSES: Please notify William Stahnke (see **FOR FURTHER INFORMATION CONTACT**) by Friday, July 16, if you plan to attend the webinar. Instructions on how to access the meeting will be emailed to meeting participants before the meeting occurs.

FOR FURTHER INFORMATION CONTACT: William Stahnke, West Coast Region, NMFS, at *william.stahnke@noaa.gov,* or at (562) 980–4088.

SUPPLEMENTARY INFORMATION: The timing of U.S. SAS and GAC meetings is dependent on when IATTC annual meeting(s) occur. This year, the 98th Annual Meeting of the IATTC will take place from August 23–27, 2021. As such, the combined U.S. SAS and GAC Meeting will be held before the 98th IATTC Annual Meeting. It should be noted that while the 97th (Extraordinary) IATTC Meeting was focused solely on tropical tuna (*i.e.,* bigeye, yellowfin, skipjack tuna) measures, the 98th Annual Meeting of the IATTC will cover additional topics.

In accordance with the Tuna Conventions Act (16 U.S.C. 951 *et seq.*), the U.S. Department of Commerce, in consultation with the Department of State (the State Department), appoints a GAC to the U.S. Section to the IATTC and a SAS that advises the GAC. The U.S. Section consists of the four U.S. Commissioners to the IATTC and representatives of the State Department, NOAA, Department of Commerce, other U.S. Government agencies, and stakeholders. The GAC advises the U.S. Section with respect to U.S. participation in the work of the IATTC, focusing on the development of U.S. policies, positions, and negotiating tactics. The purpose of the SAS is to advise the GAC on scientific matters. NMFS West Coast Region staff provide administrative support for the SAS and GAC. The meetings of the SAS and GAC are open to the public, unless in executive session. The time and manner of public comment will be at the discretion of the Chairs for the SAS and GAC.

For more information and updates on these upcoming meetings, please visit the IATTC's website: *https://www.iattc.org/MeetingsENG.htm.*

SAS and GAC Meeting Topics

This meeting will have a reduced agenda to prepare for the 98th IATTC Meeting that is expected to focus on tropical tuna, but will cover other topics as well.

The meeting agenda will include, but is not limited to, the following topics:

(1) Relevant scientific information from the IATTC scientific staff and the International Scientific Committee for Tuna and Tuna-Like Species in the North Pacific Ocean (ISC) for tuna, tuna-like species, and other species caught in association with those fisheries in the eastern Pacific Ocean;

(2) Discussion of management measures for tropical tuna, temperate tuna (*e.g.,* North Pacific albacore and Pacific bluefin tuna), and sharks as well as administrative topics;

(3) Recommendations and evaluations by the SAS and GAC; and

(4) Other issues as they arise.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to William Stahnke (see **FOR FURTHER INFORMATION CONTACT**).

Authority: 16 U.S.C. 951 *et seq.*

Dated: July 20, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021–15747 Filed 7–20–21; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Deep Seabed Mining Exploration Licenses

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on April 23, 2021, (86 FR 21706) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration, Commerce.

Title: Deep Seabed Mining Exploration Licenses.

OMB Control Number: 0648–0145.

Form Number(s): None.

Type of Request: Regular submission (extension of a currently approved collection).

Number of Respondents: 1.

Average Hours per Response: Annual report: 40 hours; extension request: 20 hours (annualized).

Total Annual Burden Hours: The annual total time for license holders to prepare paperwork related to meeting the requirements of DSHMRA is 60 hours (40 hours per annual report and 20 hours (on an annualized basis) for extension requests).

Needs and Uses: This request is for the extension of the currently approved information collection. No changes have been made to the collection requirements. NOAA's regulations at 15 CFR 970 govern the issuing and monitoring of exploration and production licenses under the Deep Seabed Hard Mineral Resources Act. The NOAA Office for Coastal Management is responsible for approving and administering licenses. Any persons seeking a license must submit certain information that allows NOAA to ensure the applicant meets the standards of the Act. Licensees are required to conduct monitoring and make reports, and they may request revisions, transfers, or extensions of licenses. Information required for the issuance and extension of licenses is provided to fulfill statutory requirements to ensure that license applicants have identified areas of interest for deep seabed hard mineral exploration and production; developed plans for those activities; have the financial resources available to conduct proposed activity; and have considered the effects of the activity on the natural and human environment. This information is used to determine whether licenses should be granted or extended.

Exploration licenses and commercial recovery permits under the Deep Seabed Hard Mineral Resources Act are only for activities by U.S. citizens in international waters. No license or permit applications have been received since the early 1980s, and none are expected during this collection period. U.S. deep seabed exploration licenses and commercial recovery permits are not recognized by the International Seabed Authority and would not have security of tenure due to the lack of U.S. accession to the United Nations Convention on the Law of the Sea Treaty. Two exploration licenses issued in the early 1980s are held by Lockheed Martin Corporation. The licenses are subject to annual reporting requirements and extension requests every five years. No at-sea exploration is authorized under the licenses without further authorization from NOAA. Such activities are not expected during the reporting period for the same reason as above.

Affected Public: Large businesses.

Frequency: Report on activities pursuant to the exploration licenses due annually. Extension requests must be submitted every five years.

Respondent's Obligation: Required to maintain licenses.

Legal Authority: Deep Seabed Hard Mineral Resources Act (DSHMRA) (30 U.S.C. 1401–1473); 15 CFR part 970.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0145.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–15707 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB253]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

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

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application submitted by Nordic, Inc. in partnership with the Coonamessett Farm Foundation contains all of the required information and warrants further consideration. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act require publication of this notification to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before August 9, 2021.

ADDRESSES: You may submit written comments by the following method:

- *Email: nmfs.gar.efp@noaa.gov.* Include in the subject line ''Nordic Scallop Transplanting EFP.''

FOR FURTHER INFORMATION CONTACT: Shannah Jaburek, Fishery Management Specialist, *shannah.jaburek@noaa.gov,* (978) 281–9135.

SUPPLEMENTARY INFORMATION: Nordic, Inc. submitted a complete application for an Exempted Fishing Permit (EFP) to conduct commercial fishing activities that the regulations would otherwise restrict. This EFP would exempt the participating vessels from: Day-at-sea requirements at 50 CFR 648.53; crew size restrictions at § 648.51(c); scallop fishing restrictions in the Nantucket Lightship Closed Area—South at § 648.60(g); scallop trawl restrictions at § 648.51(a)(1) and (f); scallop dredge restrictions at § 648.51(b)(2) and (b)(3); and minimum size and possession restrictions for onboard sampling and scallop transplanting in § 648 subparts B and D through O.

Nordic, Inc., Eastern Fisheries, Quinn Fisheries, and Fulcher Trawling applied for an EFP on April 22, 2021, to work with the Coonamessett Farm Foundation (CFF) on a scallop transplanting study. This project would continue previous scallop transplanting work done by CFF and investigate the feasibility of using scallop transplanting to increase scallop growth by moving them from deep, scallop dense areas to shallower, less populated areas.

The proposed EFP would allow Nordic, Inc. and CFF to transplant 750,000 scallops in the Nantucket Lightship Access Area-South with trawls and a dredge. A subsample of the catch would be tagged (*i.e.,* 10,000 scallops), along with a subsample of previously transplanted scallops caught in the proposed research area. Transplanting work would begin when an EFP is issued, and monitoring of the harvest and transplant areas would occur during scallop Research Set-Aside (RSA) funded surveys conducted by CFF, the Virginia Institute of Technology, and the University of Massachusetts at Dartmouth School of Marine Science and Technology.

CFF would provide scientific staff to oversee transplant operations, tag scallops, and collect data during field operations. Scallops would be harvested by a commercial scalloping vessel that already preformed transplanting operations. Four vessels would harvest scallops with a two-panel box net towed between 2.5 and 3.5 knots (4.6 and 6.5 km per hour) for 10 minutes per tow. These vessels would steam to the transplant area with the trawl doors closed and the net remaining in the water. One vessel would harvest scallops by towing two, 4.57-meter wide New Bedford style dredges for 10 minutes per tow. No catch will be landed for sale.

Once catch is brought on board, it would be sorted by size, marked, and stored in cooled fish totes. A subsample of scallops would be tagged with disc tags. Tagging would occur between dusk and dawn to minimize mortality. Scallops would be released overboard at the transplanting area.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the year. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

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

Dated: July 20, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021–15725 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA349]

2020 Marine Mammal Stock Assessment Reports

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

ACTION: Notice; response to comments.

SUMMARY: As required by the Marine Mammal Protection Act (MMPA), NMFS has considered public comments for revisions of the 2020 marine mammal stock assessment reports (SAR). This notice announces the availability of 80 final 2020 SARs that were updated and finalized. NMFS also announces the availability of a revised final 2019 North Atlantic right whale SAR that includes a typographic correction.

ADDRESSES: Electronic copies of SARs are available on the internet as regional compilations and separated by individual species/stocks at the following addresses, respectively: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-species-stock.*

FOR FURTHER INFORMATION CONTACT: Dr. Zachary Schakner, Office of Science and Technology, 301–427–8106, *Zachary.Schakner@noaa.gov;* Marcia Muto, 206–526–4026, *Marcia.Muto@noaa.gov,* regarding Alaska regional stock assessments; Elizabeth Josephson, 508–495–2362, *Elizabeth.Josephson@noaa.gov,* regarding Atlantic, Gulf of Mexico, and Caribbean regional stock assessments; or Jim Carretta, 858–546–7171, *Jim.Carretta@noaa.gov,* regarding Pacific regional stock assessments.

SUPPLEMENTARY INFORMATION:

Background

Section 117 of the MMPA (16 U.S.C. 1361 *et seq.*) requires NMFS and the U.S. Fish and Wildlife Service (FWS) to prepare stock assessments for each stock of marine mammals occurring in waters under the jurisdiction of the United States, including the U.S. Exclusive Economic Zone (EEZ). These reports must contain information regarding the distribution and abundance of the stock, population growth rates and trends, estimates of annual human-caused Mortality and Serious Injury (M/SI) from all sources, descriptions of the fisheries with which the stock interacts, and the status of the stock. Initial reports were completed in 1995.

The MMPA requires NMFS and FWS to review the SARs at least annually for strategic stocks and stocks for which significant new information is available, and at least once every three years for non-strategic stocks. The term ''strategic stock'' means a marine mammal stock: (A) For which the level of direct human-caused mortality exceeds the potential biological removal level or PBR (defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (OSP)); (B) which, based on the best available scientific information, is declining and is likely to be listed as a threatened species under the Endangered Species Act (ESA) within the foreseeable future; or (C) which is listed as a threatened species or endangered species under the ESA. NMFS and the FWS are required to revise a SAR if the status of the stock

has changed or can be more accurately determined.

Prior to public review, the updated SARs under NMFS' jurisdiction are peer-reviewed within NMFS Fisheries Science Centers and by members of three regional independent Scientific Review Groups (SRG), established under the MMPA to independently advise NMFS on information and uncertainties related to the status of marine mammals.

The period covered by the 2020 SARs is 2014–2018. NMFS reviewed all strategic stock SARs and others as appropriate and updated 80 SARs representing 84 stocks in the Alaska, Atlantic, and Pacific regions to incorporate new information. The 2020 revisions to the SARs consist primarily of updated or revised estimates of human-caused M/SI new stock names, new methodology and updated abundance estimates. Four stocks changed status from ''non-strategic'' to ''strategic'' (Eastern Bering Sea beluga whale, Gulf of Mexico spinner dolphin, Gulf of Mexico striped dolphin, and Gulf of Mexico Clymene dolphin).

The revised draft 2020 SARs were made available for public review and comment for 90 days (85 FR 78307, December 4, 2020). NMFS received comments on the draft 2020 SARs through March 8, 2021 and has revised the reports as necessary. This notice announces the availability of 80 final 2020 reports, which are available on NMFS' website (see **ADDRESSES**). The Gulf of Maine humpback whale SAR was not finalized because of a technical error; the corrected report will be published in a subsequent SAR cycle. NMFS also announces the availability of the revised final 2019 NARW SAR that includes a typographic correction.

Comments and Responses

NMFS received letters containing comments on the draft 2020 SARs from the Marine Mammal Commission (Commission); Department of Fisheries and Oceans Canada (DFO); Makah Indian Tribe (Makah); Western Pacific Regional Fishery Management Council (WPRFMC); Natural Resources Defense Council (NRDC); two fishing industry associations (Hawaii Longline Association (HLA) and Maine Lobstermen's Association (MLA)); and a coalition comment letter from four non-governmental organizations (Center for Biological Diversity, Whale and Dolphin Conservation, Conservation Council for Hawai'i, and Conservation Law Foundation, referred to hereafter as ''the Coalition''). Responses to substantive comments are below; responses to comments not related to the SARs are not included. Comments suggesting editorial or minor clarifying changes were incorporated in the reports, but they are not included in the summary of comments and responses. In some cases, NMFS' responses state that comments would be considered or incorporated in future revisions of the SARs rather than being incorporated into the final 2020 SARs.

Comments on National Issues

Comment 1: The Coalition notes that the MMPA requires that NMFS revise stock assessments for strategic stocks annually and comments that the public is not able to timely contribute to the SARs. For those stocks, which are especially important to conserve, the public is not able to timely contribute to the SARs. The publication of the draft SARs is same month as the Scientific Review Groups are reviewing the draft 2021 marine mammal SARs and the coalition commented that undermines the public's ability to participate in a meaningful manner.

Response: The MMPA requires NMFS to review, not revise, SARs at least annually for strategic stocks and stocks for which significant new information is available. Following this review, NMFS revises SARs as necessary. We acknowledge and agree with this comment regarding the importance of following the SAR process timeline so the current year's draft SARs do not overlap with the final SARs from the previous year. Unfortunately, the publication of the draft 2020 SARs was delayed until the end of the year, largely due to the impacts of the ongoing COVID–19 pandemic. The public comment period of 90 days, however, remained unchanged.

Comment 2: The Commission continues to be concerned about NMFS' performance in meeting several of the requirements of Section 117 of the MMPA. Without a minimum abundance estimate (Nmin) derived from recent data, PBR cannot be calculated and is considered ''unknown.'' Including the revised 2020 draft SARs, the Commission comments that an Nmin estimate is lacking for 81 of the 252, or 32 percent of identified stocks. The lack of data for over one third of the stocks recognized by NMFS is a serious shortcoming in meeting statutory obligations. The Commission reiterates its recommendation that NMFS continue its efforts to prioritize and coordinate requests to secure the necessary survey resources across regions.

Response: We acknowledge the Commission's comment and will continue to prioritize our efforts for the collection of data to address outdated Nmin estimates, as resources allow.

Comment 3: The Commission notes that in a few of the individual SARs (*e.g.,* Eastern North Pacific gray whale, CA/WA/OR fin whale, and all of the Northeast stocks), M/SI data are lumped for the five-year analysis period. The Commission feels strongly that M/SI data should be presented individually for each year of the analysis period, and comments that the detection of short-term trends or extreme events affecting M/SI are difficult to discern if five-year averages are the only data available. The Commission recommends that NMFS present estimates for each year of a five-year analysis period for all SARs with M/SI data.

Response: For two of the stocks highlighted by the Commission (Eastern North Pacific gray whale and CA/WA/OR fin whales), the number of observed bycatch events in the most-recent five-year period (one and zero respectively) are highlighted in the SAR bycatch table for the California swordfish drift gillnet fishery that is observed annually. For the sake of visual simplicity in the SAR (rather than parsing out five zeros or four zeros and a one), these data are pooled into a five-year time frame and individual annual totals may be found in supporting citations (bycatch and serious injury reports). In cases where there has been a large spike in bycatch, or major changes in fishery effort or observer coverage, these details are reflected in the SAR text. Where MS/I data are collected opportunistically from strandings or at-sea sightings, the five-year sum of observed totals is assessed against PBR and individual year data is published in annual serious injury reports. We agree that in some cases where observer coverage is sporadic or highly-variable within a five-year period, parsing out such annual data may be useful to highlight potential data gaps or changes in bycatch levels. However, these benefits are outweighed by the costs of parsing and presenting annual data that is prone to high levels of statistical noise.

Comments on Alaska Issues

Comment 4: Over the past decade, the Commission has repeatedly recommended that NMFS, in collaboration with its co-management partners, improve its monitoring and reporting of subsistence hunting in Alaska. While there have been improvements in the number of communities reporting take levels for some ice seals in the SARs in recent years, the majority of communities that hunt or may hunt ice seals are still unaccounted for. Therefore, the

Commission continues to recommend that NMFS pursue additional mechanisms to gather reliable information on the numbers of marine mammals taken for subsistence and handicraft purposes, including by securing adequate funding for comprehensive surveys of subsistence use and Native hunting effort in collaboration with co-management partners and the State of Alaska.

Further, the Commission encourages NMFS to continue to provide updated information in the SARs whenever it becomes available, even if it pertains only to a limited number of villages or a subset of years. The Commission has previously recommended that NMFS include all available data about harvest numbers, including struck and lost, in the SARs for beluga whales, and that NMFS work with the Alaska Beluga Whale Committee to improve the completeness of and consistency in reporting harvest data, with a focus on struck and lost information for these stocks. The Commission understands that, in response to a recommendation from the Alaska SRG, struck and lost numbers will be included in the final 2020 SARs and the Commission looks forward to seeing those numbers.

Response: NMFS agrees that it is important to collect reliable information on the numbers of marine mammals taken for subsistence and handicraft purposes. Funding for subsistence use surveys remains limited; thus, in most cases, the best available data are not comprehensive. Nevertheless, we continue to work with our Alaska Native co-management partners (and the State of Alaska in some cases) to conduct surveys of subsistence use as resources allow, including animals struck and lost, and we incorporate that information into the SARs as it becomes available.

Comment 5: The Coalition emphasizes that, in the Humpback Whale, Central North Pacific Stock SAR, the section on habitat concerns should include Currie *et al.* (2021), which showed that in the presence of vessels, humpback whales increase swim speed and respiration rate and decrease dive times, which has been shown to be an energetically demanding avoidance strategy. In order to ensure recovery to OSP, the Coalition comments that the SARs must include non-lethal effects of human disturbance, as described in Currie *et al.* (2021) and believes that recording those interactions is a first step toward assessing and mitigating the severity of impact. The Coalition also requests that the Habitat Concerns section include the increasing overlap between whales and high concentrations of marine debris.

Response: NMFS has added information on (1) the behavioral responses of humpback whales to vessel presence in Southeast Alaska and Hawaii (Schuler *et al.* 2019, Currie *et al.* 2021), and (2) the overlap between humpback whales and high concentrations of marine debris (Currie *et al.* 2017) to the Habitat Concerns section of the final 2020 Central North Pacific humpback whale SAR.

Comments on Atlantic Issues

North Atlantic Right Whale, Western Atlantic Stock

Comment 6: Department of Fisheries and Oceans Canada (DFO) notes that Entanglement Mortality #3893 (1/22/2018) was discovered on a U.S. beach (1/22/2018) with no gear recovered but was assigned to Canada. DFO is not aware of any conclusive evidence to support this death being attributed to Canada.

Response: NMFS thanks the reviewer for the detailed examination of individual cases. Gear was recovered from #3893 and identified as Canadian snow crab fishing gear.

Comment 7: DFO comments on Entanglement Prorated Injury #3312, which was sighted in Canadian waters (7/13/2018) with no gear recovered and then assigned to Canada (CN). Entanglement Prorated Injury #3843 was sighted in Canadian waters (7/30/2018), also with no gear recovered, and it was unassigned as a first sighting in Canada (XC). DFO is not aware of any conclusive evidence to suggest that #3312 would reasonably be assigned to Canada. Moreover, a seemingly similar case of Entanglement Prorated Injury in U.S. waters (12/20/2018, #2310, Nantucket, MA), where there was also no gear recovered but was first sighted in the United States, is marked as unassigned (XU).

Response: Entanglement Prorated Injury #3312 was sighted in Canada earlier in the day on 7/13/2018 gear free. NMFS determined the entanglement occurred within a 2-hour window that day, thus it was assigned to CN. The other two whales sighted as examples had pre-entanglement sighting histories >1 month; therefore, there was much more uncertainty about when and where the entanglement may have occurred.

Comment 8: DFO comments on the summary in Table 3. Confirmed human-caused M/SI records of right whales: 2014–2018a assigns a 1.55 average M/SI over 5 years due to entanglement to Canada. Looking at the incidents in the table marked EN (entanglement) CN (Canada) there are 6.75 incidents (4 mortalities + 2 serious injuries + 0.75 prorated injury), resulting in an average of 1.35 per year rather than 1.55. The discrepancy is carried over from the 2019 draft SAR, when #3694 mortality was assigned to Canada. However, in response to DFO's comment related to the mortality assignment of #3694 (published 85 FR 149; August 3, 2020.), the entry for #3694 was changed from CN (assigned to Canada) to XC (Unassigned first sighted in Canada) in the final 2019 North Atlantic right whale Stock Assessment Report. DFO points out that the total counts have not been updated in the summary for the 2020 draft SAR.

Response: Right whale #3694 was changed from XU (unassigned, first sighted in US) to CN in the 2019 draft that went out for public comment based on identification of the gear as Canadian snow crab gear. In the conversion from draft to final, this was inadvertently changed to XC (unassigned, first sighted in Canada). A correction has been issued and we have made the changes to the final 2019 report which is now available. Summary statistics have also been corrected in the final 2020 report.

Comment 9: DFO is not aware of any conclusive evidence used in assigning the following to Canada: Serious Injury #4057 (8/13/2016) and Serious Injury #4094 (07/19/2017).

Response: The gear involved with Serious Injury #4057 (8/13/2016) was identified as Canadian crab pot by DFO. For Serious Injury #4094 (07/19/2017), the gear was identified as Canadian crab pot in Daoust *et al.* (2018).

Comment 10: The Coalition recommends that the section ''Stock Definition and Geographic Range'' be changed to reflect the current habitat use of right whales. As written, it is confusing to discern between historic and more recent data. For example, the introduction states that foraging habitat is in New England and Canadian waters, which does not address the year-round use of waters south of Cape Cod as a foraging habitat as reflected in the NOAA Expert Working Group Report, or the detections in all seasons of right whales in the near shore waters of New Jersey during which right whales were documented skim feeding. The Coalition comments that the mid-Atlantic is increasingly used by the species as more than a migratory corridor, which should be reflected in the SAR. The current references to the mid-Atlantic in the draft SAR precede 2010, the time when a significant shift in right whale habitat use was first noted. More recent sightings of right whales in the Gulf of Mexico and off the

Canary Islands should also be included. The Coalition also notes that it is important to consider that population demographics may dictate habitat use, which could impact associated risks to those individuals.

Response: Although NMFS considers the description of the right whale range and habitat use to be an accurate reflection of published findings to date, we acknowledge that new observations indicate additional changes in the species' seasonal distribution. We also agree that demographics are an important consideration. Several studies have been recently completed; but, until published, our ability to utilize this information in the SAR is limited. In addition, we have no evidence to suggest that ''changing habitat use'' has settled into a new stable state. Still, we endeavor to consider all significant changes in habitat use. When it comes to management decisions based on habitat use, the agency uses the most current habitat use models available including those from the Marine Geospatial Ecology Lab at Duke University, which does reflect an increase in habitat use in the mid-Atlantic region.

Comment 11: The Coalition comments that the ''Population Size and PBR'' section is outdated and does not reflect the most recent analysis indicating that the Nmin for 2019 is 347. Even considering 2018, the value in the SAR is higher than the best population estimate of 383 based on the Pace method (Pace *et al.* 2021). As such, PBR is below 0.8.

Response: NMFS strives to update the SARs with as timely data as possible, to ensure the SARs are based upon the best available scientific information. As noted in previous years, as a result of the review, revision, and assessment of available data, the data used typically lag two years behind the year of the SAR. The agency recognizes the lags in SAR processing time, but this is necessary to achieve the appropriate peer review. To that extent, we are finalizing a NMFS technical memorandum to provide up-to-date population estimates. We expect to include these data and information in the 2021 SAR.

Comment 12: The Coalition appreciates NMFS' inclusion of cryptic mortality as calculated by Pace *et al.* (2021). The current reference in the document should be updated from submitted to reflect its publication.

Response: Now that Pace *et al.* (2021) is published, we have updated the reference.

Comment 13: The Coalition asks NMFS to update the ''Fishery-Related Mortality and Serious Injury'' section to include Hamilton *et al.* (2019), from which NMFS determined that ''11.04 percent of the right whale population is entangled annually in U.S. federal fishing gear.'' The Coalition requests that NMFS include its findings that an average of 6.724 right whales are seriously injured or killed in U.S. fishing gear each year.

Response: We have updated language in the final 2020 SAR referencing observations by Hamilton *et al.* (2019) that 30.25 percent of the population was entangled annually between 2010 and 2017. We recognized in the text of the document that MS/I is likely much higher than observed. However, the estimates above are based on a NMFS 2021 analysis that is still a draft and was not reviewed by the Atlantic SRG at the time of writing. Approaches to these issues were discussed with recommendations made by the Atlantic SRG in 2021 that will be considered in the 2021 SAR.

Comment 14: The Coalition asks NMFS to include the findings in the recently published North Atlantic Right Whale (*Eubalaena glacialis*) Vessel Speed Rule Assessment, which concluded that voluntary measures did not have a meaningful impact on reducing vessel collisions, small vessel collisions can seriously injure right whales, and that the current SMAs should be modified.

Response: We appreciate this comment; the implications of the Vessel Speed Rule Assessment are being considered for the 2021 SAR.

Comment 15: The Coalition requests that the 2018 prorated injuries for the following whales be changed to a value of 1 against PBR to reflect NMFS' determination that these individuals meet the criteria of Seriously Injured, as reflected on the Agency's Unusual Mortality Page: #3312 (entanglement), #3843 (entanglement), and #2310 (entanglement).

Response: NMFS' Unusual Mortality Event (UME) web page is currently tallying prorated injuries and serious injuries together; but, for the SARs, NMFS follows the assessment guidelines here: *https://media.fisheries.noaa.gov/dam-migration/02-238-01.pdf.*

Comment 16: NRDC requests that NMFS revise the draft North Atlantic right whale SAR to reflect the most up-to-date estimate of population size. The best population estimate for the end of 2019 is now just 356 individuals, representing a more ''precipitous drop [in the population size] than previous years.'' Moreover, the best population estimate for the end of 2018 has been revised down from 409 individuals to 380 individuals. NRDC comments that the new 2019 and revised 2018 estimates indicate a significant decrease in survivorship during the last three years as a result of the ongoing unusual mortality event. NRDC emphasizes that NMFS should update the draft SAR according to the best available scientific information on North Atlantic right whale population size.

Response: See our response to comment 11.

Comment 17: NRDC requests that NMFS revise the PBR level downward for the NARW. The updated population size estimate has implications for the calculation of the PBR level for the North Atlantic right whale. NMFS' draft SAR states that PBR for the species is currently 0.8; however, the agency has acknowledged in other fora that the most recent population estimate has further reduced PBR to 0.7. NMFS must revise the PBR level in the draft SAR downwards to reflect the best available scientific information.

Response: We appreciate this comment; please see our response to comment 11.

Comment 18: NRDC comments that NMFS must accurately account for cryptic mortalities in its calculation of ''total'' estimated human-caused mortality and serious injury. The number of observed mortalities is a significant underestimate of actual deaths. A scientific study published this year by Richard Pace and colleagues (Pace *et al.* 2021) concludes only 29 percent (2 standard errors = 2.8 percent) of right whale carcasses were detected from 2010 to 2017. The same study found that entanglements accounted for the ''vast majority'' of detected serious injuries (87 percent), but only about half of detected deaths (49 percent) from 1990 to 2017. Thus, ''cryptic deaths due to entanglements significantly outnumbers cryptic deaths from vessel collisions or other causes.'' NMFS must update the estimates of ''total'' mortality included in the draft SAR based on the findings of the new Pace *et al.* (2021) model.

Response: NMFS appreciates this request. While Pace *et al.* (2021) make reference to the regime period of 2010–2017, the SARs—which work on 5-year rolling averages—make use of the time period 2013–2017. As such, the numbers in the SAR are not in disagreement with the estimates in Pace *et al.* 2021. Recognizing the significance of the population decline, we intend to publish a NMFS Technical Memorandum (Pace, in press) to provide an update on these estimates, as resources allow. We expect to reference

this NMFS Technical Memorandum in a future SAR.

Comment 19: NRDC notes that NMFS must include the best available scientific information on sublethal impacts of entanglement. Entanglement remains the leading cause of North Atlantic right whale mortality and a major factor in reproductive loss. NRDC notes the pervasive sub-lethal effects of entanglement, including impaired reproductive potential and negative health effects, currently undermine any opportunity for the species to recover and may eventually lead to individual mortalities. NRDC emphasizes that NMFS must include, and should more thoroughly consider, the best available scientific information on sub-lethal effects of entanglement and the implications for the survival of the North Atlantic right whale in the draft SAR.

Response: This is a valid point, and sub-lethal effects of entanglement was acknowledged in the ''Current and Maximum Net Productivity Rates'' section. NMFS had not yet cited the work by Christiansen *et al.* (2020), so we added that reference in the final 2020 SAR.

Comment 20: The Commission is hopeful that its recommendations and those of other experts will compel NMFS to take decisive and effective steps toward enabling right whales to recover. In that effort, it is imperative that NMFS apply the best available data and science to its estimation of population size and the M/SI rate. The best available population estimates are provided by the population model developed by Pace *et al.* (2017), and NMFS is making use of those estimates. NMFS has always done an excellent job of estimating the number of known M/SI due to entanglement in fishing gear and due to vessel strikes. However, a secondary finding of the Pace *et al.* (2017) population model was that only 60 percent of the total mortality estimated by the model was accounted for by the known M/SI. It was long suspected that some mortalities were going undetected, and the Pace *et al.* (2017) model suggested that the undetected proportion was 40 percent. Therefore, the Commission recommends that NMFS immediately take steps to include the best available science by incorporating the Pace *et al.* (2021) estimates of undetected mortalities in its estimates of total human-caused mortality and serious injuries of right whales in the final 2020 SAR.

Response: Please see NMFS response to comment 18.

Comment 21: MLA comments that the draft SAR must include more information regarding NARW entanglements in fishing gear. The draft SAR contains none of the statutorily required information on commercial fisheries that interact with the stock (16 U.S.C. 1386(a)(4)). As a result, the public has no information about the fisheries that interact with the NARW and the levels, types, and seasonal and geographic patterns of entanglement that occur within and among those fisheries. This information must be included in the final SAR.

The draft SAR presents only M/SI entanglement data—non-serious injury entanglements are omitted. This highly important information is relevant to assess the effectiveness of the Atlantic Large Whale Take Reduction Plan (TRP). For example, the TRP requires certain measures that are intended to reduce the severity of fishery interactions, rendering them non-serious injuries. MLA emphasizes that a comparison of M/SI and non-serious injury data over time, by area, and by fishery, is relevant to evaluating the effectiveness of measures intended to reduce the severity of fishery interactions. This information must be included in the final SAR.

Response: Because there are multiple species interactions with multiple fisheries, the fisheries are summarized in Appendix 3—Fishery Descriptions. They are also available online *https://www.fisheries.noaa.gov/national/marine-mammal-protection/list-fisheries-summary-tables* with focus on Table II category I and II fisheries. The SAR reports to the extent possible what information is available for describing commercial fisheries that interact with the stock, in accordance with Section 117 of the MMPA (*i.e.,* M/SI levels by fishery, seasonal/area differences in M/SI, and M/SI rates calculated using standardized fishing effort). However, because only a small fraction of entanglements have gear recovered and a smaller fraction of that is traceable to the fishery, the agency has not been able to estimate the annual MS/I to the resolution of fishery/region. Given new recommendations from the Atlantic SRG meeting in 2021, and additional analysis resulting from Pace *et al.* (2021), NMFS is working to improve our reporting of this issue in future SARs. For now, this topic is addressed to the extent that data can support it in the SAR's Table 3. The issue of non-serious injuries is discussed in the third paragraph of the section titled ''Fishery-Related Mortality and Serious Injury.'' The draft SAR cites Knowlton *et al.* (2016) and more recently Hamilton *et al.* (2019), which have consistently tracked 26 percent to now 30 percent of the population receiving non-serious injuries annually, which is an increasing trend. Despite roughly 100 injuries per year in recent years, injuries are almost never observed at the time they occur, but the wounds persist for periods of weeks to months/years, during which time animals may travel thousands of miles. Additional language to address this concern has been added to the first paragraph of the ''Fishery-Related Mortality and Serious Injury'' section of the SAR.

Comment 22: MLA requests that the SAR include data on the severity of entanglements. The New England Aquarium (2020) reports that from 2010 to 2017, the annual average serious entanglement rate ranged from 1.4 percent to 3.8 percent, and that from 2014–2018 the majority of NARW entanglements were minor (62 percent), with less than half either moderate or severe (19 percent and 19 percent, respectively). None of this important information is reported in the draft SAR, but it should be.

Response: Table 3 of the NARW SAR provides considerable detail on each entanglement case that merited a prorated serious injury or greater. The New England Aquarium applies different criteria than defined in NMFS' Serious Injury Policy (NMFS 2014). While there is often agreement between institutions, inconsistencies occur based on different criteria. The ''rates'' quoted above are based upon observed events. However, Pace *et al.* (2021) stated, ''We used an abundance estimation model to derive estimates of cryptic mortality for NARW and found that observed carcasses accounted for only 36 percent of all estimated deaths during 1990–2017. We found strong evidence that total mortality varied over time, and that observed carcass counts were poor predictors of estimated annual numbers of whales dying.'' As such, focusing on the rates above would amount to 'cherry picking' and misleading conclusions that under-represent the true scale of the entanglement problem, given that Pace *et al.* (2021) indicate only 36 percent of mortalities have been observed since 1990, and given the bias that most serious injuries are entanglements (vs. ship strikes) that are never seen again. This indicates hundreds of entanglement mortalities have gone undetected even in just the past decade.

Comment 23: MLA points out that the Guidelines for Assessing Marine Mammal Stocks (GAMMS) instruct authors to include in the SAR ''[a] summary of mortality and serious injury incidental to U.S. commercial fisheries . . . presented in a table, providing the name of the fishery and, for each appropriate year, observed mortality

and serious injury, estimated extrapolated mortality and serious injury and associated CV, and percent observer coverage in that year, with the last column providing the average annual mortality and serious injury estimate for that fishery.'' Although the draft SAR presents a table of entanglements showing ''country'' and ''gear type,'' this falls well short of the detailed and well-organized table recommended by GAMMS (and included in numerous other SARs). MLA notes that such a table should be included in the SAR. This information is important for assessing individual fisheries, which has even more significance given that NMFS' revised ''negligible impact determination'' policy includes a process for assessing individual fisheries.

Response: Table 3 provides all known information on injuries. The requested table is not provided because the data are not available to populate it. Appendix 3 describes the U.S. fisheries and their observer coverage level (or the complete lack thereof, in the case of the lobster fishery). Additional language to address this concern has been added to the first paragraph of the ''Fishery-Related Mortality and Serious Injury'' section of the SAR.

Comment 24: With respect to the lobster fishery, MLA requests that the SAR include data showing that there has been a 90 percent decline in instances where lobster gear was removed from entangled NARW since 2010. There were four known cases of lobster gear removed from NARW from 1997 to 2000, six from 2000–2010, and one from 2010 to 2019. MLA notes that the only confirmed M/SI resulting from entanglement in lobster gear occurred in 2002 and none of this is reported in the draft SAR.

Response: The right whale SAR provides summaries of all available data relating to right whale serious injury and mortalities during 2014–2018, including all identified fisheries. NMFS has included in the narrative the primary points and statistics. Because right whale injuries are rarely witnessed, we have relied on opportunistic reports to build our understanding of impacts to the population and provide a minimum number of deaths. However, 11 opportunistic records since 1997, as cited by the commenter, are insufficient to assess trends in entanglement rates, especially without context on fishing effort during the same time period. Specifically, gear was only retrieved from 13 percent of the right whale entanglement incidents from 2010 to 2018 (22/167). Of those, most (73 percent) are identifiable to a fishery. However, the work by Pace *et al.* (2021) shows there is no evidence of observed rates/causes of mortality corresponding to cryptic mortality rates. As such, the reporting of ''trends'' for observed cases is misleading.

Comment 25: MLA comments that the draft SAR omits data and information collected by NMFS showing that more entanglements occur with Canadian fishing gear. The draft SAR is virtually silent on the outsized role of Canadian fisheries in a significant spike in M/SI incidents since 2017, even though relevant data, scientific observations, and expert analyses are available to NMFS. This should be included in the final SAR in order to provide a full and accurate picture of the known and/or probable origin of entanglements outside U.S. waters.

Response: The final SAR assigns fishing gear to fishery type, *e.g.,* pot/trap and country of origin, when sufficient data are available. Given the low frequency at which such data are available, and the lack of a statistical relationship between observed and actual mortalities (Pace *et al.* 2021), no annual serious injury and mortality statistics are derived on a 'by fishery' basis. All confirmed Canadian mortalities were identified in Table 3. Differences in survey effort between Canada and the United States need to be considered when attempting to compare incidents of M/SI. The apparent increase in M/SI incidents in Canadian fisheries since 2017 is influenced in part by the increased detection of mortalities that happened within the confines of a relatively closed body of water that had several aircraft surveying it beginning in 2017, and as many as 5 aerial survey platforms conducting regular surveys since then. Increased Canadian monitoring efforts were in response to this being an area of significant mortality. However, the coastal waters of New England represent a similar length of area, with a similar number of vertical lines. The lack of fishery observers, much more limited aerial survey capacity over an open section of coast with currents that can carry carcasses offshore, and gear that is heavy enough to anchor whales below the surface contributes to making coastal New England waters an area where the odds of detecting mortality are quite low. However, spatial models suggest a high risk of mortality in this area. As above, we note that many of these comments recommend placing strong correlation value on limited observations, which is ill advised based upon the findings of Pace *et al.* (2021).

Comment 26: MLA comments that although the draft SAR acknowledges that ''[a]n Unusual Mortality Event was established for North Atlantic right whales in June 2017 due to elevated st[r]andings along the Northwest Atlantic Ocean coast, especially in the Gulf of St. Lawrence region of Canada,'' it omits discussion of significant relevant information showing that a large number of NARW have altered their migratory patterns because their preferred prey has responded to altered oceanographic conditions by moving into the Gulf of St. Lawrence, where NARW are at very high risk of entanglement in snow crab gear that is heavier and more lethal than gear fished in U.S. waters. This relates directly to the severity of injury resulting from entanglement, as noted in previous MLA comments. This information provides important insights into the source of entanglement risk and severity of entanglement for North Atlantic right whales, and MLA requests NMFS include the best available scientific information.

Response: NMFS has addressed this comment in the ''Stock Definition/Geographic Range,'' ''Current Population Trend,'' and ''Habitat Issues'' sections.

Comment 27: MLA suggests that the draft SAR should be revised to incorporate the best available scientific information regarding the increasing proportion of M/SI from Canada as a result of altered North Atlantic right whale migratory patterns to the Gulf of St. Lawrence. These data are critical to understanding the increase in M/SI. Specifically, MLA requests the inclusion of data concerning the country of origin of NARW entanglements during the relevant time period, taking into account scientific observations of entangling gear, depicting differentiating attributes of that gear (such as rope diameter and strength) which make it so lethal, and describing the differences between the conservation programs and relative effectiveness of measures to protect NARW in each country.

Response: NMFS has applied the best available science to the narrative of right whale distribution and entanglement rates, but the scientific understanding of right whale movement in the western North Atlantic is limited. Also, the timeline of mortality data for this SAR is through 2018. As future data become available and statistically meaningful trends emerge, they will be discussed in future SARs as resources allow. Although roughly a third of the population currently visits the Gulf of St. Lawrence, their residency in

surveyed areas appears to be highly variable, and we have little idea where the other two-thirds of the population is residing. We do not know the relationship between detected entanglement and mortality and what the levels are for the population as a whole. We know that mortality rates are significantly higher than the number of observed cases, but currently do not have sufficient evidence to support apportioning undetected mortality to one country or another.

Comment 28: MLA states that the draft SAR omits best available scientific information about NARW behavior that affects its risk of harm from fishing gear. MLA suggests that NMFS has not taken account of significant variances in North Atlantic right whale behavior across its migratory range. MLA requests that NMFS provide greater detail on these known foraging areas, including the number and proportion of North Atlantic right whales sighted in these areas in recent years, to ensure adequate protections are in place.

To address seasonal or area differences in incidents of M/SI, MLA requests the final SAR incorporate information such as that described above detailing geographic shifts in NARW and differing behavior in these habitats in response to oscillating oceanographic conditions across their migratory range, which places North Atlantic right whales at varying levels of risk from gear entanglement.

Response: NMFS agrees that risk is elevated where high right whale density overlaps with fishing gear. Higher gear densities also elevate risk, and heavier gear likely increases injury severity. The SAR presents our current understanding of right whale distribution and population assessment for the public and management decisions. It also describes our level of understanding of entanglement risk. Although more than 80 percent of right whales bear evidence of entanglement, there are few events where the location or depth that the whale encountered the gear is known. All reported entanglement events from 2014 to 2018 are presented in Table 3.

Comment 29: MLA notes that the draft SAR must reincorporate deleted text and include supplemental information to provide a full appreciation of the status of the North Atlantic right whale population. On page 42, the draft SAR strikes text indicating that ''the existence of important habitat areas is not presently well described,'' but nonetheless states that ''long-range matches indicate an extended range for at least some individuals'' and ''the location of much of the population is unknown during the winter.'' In the absence of new data, the MLA recommends that the deleted text remain in the document to help the reader understand that much of North Atlantic right whale habitat remains poorly understood.

Response: The new text represents NMFS' evolving understanding of right whale habitat. We continue to close knowledge gaps. Some blanket statements retained from previous versions of the SAR are no longer accurate. We endeavor to provide the most pertinent information for the reader.

Comment 30: MLA comments that on page 42, NMFS has removed language stating that the majority of right whale sightings occur within 90 kilometers (km) of the shoreline of the southeastern United States. However, at page 43, the draft SAR states that ''telemetry data have shown rather lengthy excursions, including into deep water off the continental shelf (Mate *et al.* 1997; Baumgartner and Mate 2005).'' Has NMFS received new data that warrants noting North Atlantic right whale excursions into deeper water but not that North Atlantic right whales are known to occur within 90 km of the shoreline? The MLA recommends that both are important to include in the final SAR, and NMFS should provide additional details on the number of North Atlantic right whales known to use these habitats.

Response: The SAR includes both text and a figure that describes the distribution of sightings. The statement that the majority of sightings occur within 90 km of the shoreline was misleading because it does not account for effort; most right whale sightings occur close to shore because that is where most people are present to see and report the sightings. The excursions into deep water are not otherwise well represented. Telemetry data provide another dimension to NMFS' understanding and are important to note.

Comment 31: MLA noted that, on page 43, the draft SAR states that ''New England waters are important feeding habitats for right whales, where they feed primarily on copepods (largely of the genera *Calanus* and *Pseudocalanus*).'' MLA believes the best available information allows NMFS to be more specific in this statement. Given the pending regulatory focus on offshore Maine, MLA believes it would be appropriate to distinguish where these feeding grounds occur.

Response: The narrative in the SAR is meant to provide only a general description of right whale distribution. NMFS is providing other products with detailed information on right whale densities throughout the right whales' range for management and Atlantic Large Whale Take Reduction Team consideration.

Comment 32: On page 44, the draft SAR states: ''In 2016, the Northeastern U.S. Foraging Area Critical Habitat was expanded to include nearly all U.S. waters of the Gulf of Maine (81 FR 4837, 26 February 2016).'' MLA requests that NMFS clarify that critical habitat is designated because it contains at least one physical or biological feature to support foraging, and not necessarily because NARW have been observed to forage in all designated areas throughout the entire Gulf of Maine. Some readers may not understand the regulatory criteria for designating critical habitat, which are not dependent upon whale presence.

Response: NMFS agrees with this distinction, and language has been added to this point in the final 2020 NARW SAR.

Comment 33: MLA noted, on page 44, the draft SAR states: ''An important shift in habitat use patterns in 2010 was highlighted. . . . The number of individuals using Cape Cod Bay in spring increased, (Mayo *et al.* 2018). In addition, right whales apparently abandoned the central Gulf of Maine in winter (see Cole *et al.* 2013), but have since been seen in large numbers in a region south of Martha's Vineyard and Nantucket Islands. . . . Aerial surveys of the Gulf of St. Lawrence during the summers of 2015, 2017, and 2018, documented at least 34, 105, and 131 unique individuals using the region, respectively (NMFS unpublished data).'' MLA believes NMFS should provide as much detail as possible to help the public understand the spatial distribution of North Atlantic right whales. MLA requests the inclusion of the number of North Atlantic right whales and proportion of the population sighted in Cape Cod Bay (as noted in previous MLA comments), clarify what is meant by central Gulf of Maine (which MLA interprets to be the portion of the Gulf of Maine located off the Maine coast), and include the proportion of North Atlantic right whales represented by Gulf of St. Lawrence sightings.

Response: Clarification has been added to text regarding the central Gulf of Maine location. Describing the proportion of individuals sighted in various habitats may provide a false impression of our level of knowledge of right whale use of these areas. Photographic capture of individuals and maximum likelihood models of these data indicate considerable immigration

and emigration of individuals. A tally of individuals seen in a habitat does not accurately convey the spatial distribution of right whales, or potential risk. There is a significant difference in risk levels if 10 whales occupy an area for a day versus 10 whales occupying an area for 100 days. NMFS' level of understanding is evolving and is currently better in some areas than others. The text is an accurate reflection of our current understanding when considering the combined effects of sightings, survey effort, and potential residency of right whales.

Comment 34: MLA commented that, on pages 44–45, the draft SAR strikes the language: ''an additional interpretation of paternity analyses is that the population size may be larger than was previously thought. Fathers for only 45 percent of known calves have been genetically determined; yet, genetic profiles were available for 69 percent of all photo-identified males (Frasier 2005). The conclusion was that the majority of these calves must have different fathers that cannot be accounted for by the unsampled males, therefore the population of males must be larger (Frasier 2005).'' MLA comments it is unclear why this text citing data from Frasier (2005) is struck from the SAR and why Fitzgerald (2018) now represents the best available information?

Response: NMFS has determined that Fitzgerald (2018) best represents the current understanding of pedigree-informed abundance estimation; however, Frasier (2005) has not been conclusively refuted. We have restored Frasier (2005), and added Frasier *et al.* (2007), to the text and references.

Comment 35: MLA points out that on page 56, the draft SAR states: ''Whales often free themselves of gear following an entanglement event, and as such scarring may be a better indicator of fisheries interaction than entanglement records.'' As noted previously, this statement falls short of providing a useful and complete understanding of scarring data for the relevant time period. As described above, the New England Aquarium (2020) states that the majority of entanglements between 2014 and 2018 are minor (62 percent).

Response: This is a valid point, and NMFS will include more detailed results from entanglement scar-coding research in a future draft NARW SAR, as resources allow.

Comment 36: MLA noted, on page 56, the SAR cites three studies concluding that North Atlantic right whales mitigation measures implemented prior to 2009 have not worked, and that the effectiveness of measures implemented since 2009 have not yet been evaluated. NMFS has reported on multiple occasions in conversations with the Atlantic Large Whale Take Reduction Team that the 2009 groundline rule has been effective, citing data that no groundlines have been identified as the primary entangling gear on right whales since its implementation, yet the SAR states that the effectiveness of these measures has yet to be evaluated. In addition, as noted above, the SAR should report data showing that there has been a 90 percent decline in instances of lobster gear removed from entangled North Atlantic right whales since 2010. There were four known cases of lobster gear removed from North Atlantic right whales from 1997 to 2000, six from 2000 to 2010, and one from 2010 to 2019. The only confirmed M/SI resulting from entanglement in lobster gear occurred in 2002.

Response: In this instance, the SAR is reporting on the population level effect of the groundline rule, that is, if the 2009 rule has significantly reduced entanglement rates. The absence of groundline as primary entangling gear is a positive result, but a comprehensive evaluation of effectiveness of the rule requires a long time series for a statistically robust analysis. Opportunistic records cannot provide any rate change information, such as injury rate relative to fishing levels, because the variables affecting detection are largely unknown.

Comment 37: MLA comments that the draft SAR contains errors in Table 3. First, the entanglement that occurred on 9/23/2016 (ID 3694) has been confirmed to have involved Canadian trap/pot gear since the draft SAR was published. The country code in Table 3 for this entry and the M/SI for entanglement by country of origin should be updated accordingly. Second, there is a minor clerical error that should be corrected for consistency. The entanglement that occurred on 7/30/2018 (ID 3843) is miscoded as ''-''. The correct coding for this entry is ''GU''.

Response: The gear retrieved from #3694 was identified as Canadian snow crab in April 2018. It was previously reported as XU with unknown gear but has been updated to CN pot/trap in the final 2020 SAR. The coding for 7/30/2018 (ID 3843) has been updated to ''GU'' in the final 2020 SAR.

Comment 38: MLA requests that the draft SAR disclose the current limits of the Pace model. MLA comments that the draft SAR (p. 46) could be construed by the public to mean that Pace *et al.* (2017) fully accounts for changes in capture probability. However, the Pace model is relatively new and highly sensitive to additional years of data, in part because subsequent re-sightings influence the probability of recapture and estimate of mortality.

Response: The Pace model does account for changes in capture probability (see Figure 3 in the final 2020 SAR), and builds on the full sighting history of all individual right whales to provide population estimates that are robust to changes in whale distribution and survey effort. This approach, coupled with high levels of effort to photographically capture individuals each year, provides relatively precise estimates and the ability to detect small changes in the population from year to year.

Comment 39: MLA comments that the draft SAR should make clear that while Pace *et al.* (2017) assumes no natural mortality, natural mortality has been documented by Taylor *et al.* (2013) and Curtis *et al.* (2014). The fact that there is a significant amount of neonate mortality (see draft SAR, p. 55) is critical for the public to understand. By ignoring neonate mortality, as done by the Pace model, MLA believes the below-expected number of individuals recruited into the population could be construed as a reflection of the NARW calving rate when, in fact, natural mortality is occurring. The appropriate regulatory and management responses to an anomalously low calving rate are different from elevated neonate mortality from natural predators. MLA requests the SAR cite relevant literature on natural mortality and put it in the context of studies such as Pace *et al.* (2017).

Response: First, the Pace *et al.* (2017) model does not assume any particular cause of death (natural or human-caused); it simply allows one to estimate total mortality using sighting histories as described in the draft SAR. Second, we agree that there are likely neonate mortalities that go undetected, some of which may due to natural causes. However, since these undetected neonates would not have a sighting history, including these instances would only add to the total mortality derived from the Pace *et al.* (2021) method and would not change the findings of Sharp *et al.* (2019) that all non-calf mortality for which cause of death could be determined was human-caused. To date, only one neonate mortality was determined to be from white shark predation. Pre-mortem shark attack was determined to be a contributing cause of death of two other calves that were entangled in fishing gear (Taylor *et al.* 2013). In general, calving rate in this population is determined by extensive survey effort along the coast of the

Southeastern United States, with very few individuals found to ''enter the population'' without having been detected as calves in recent years.

Comment 40: MLA points out that the SAR concludes 100 percent of the estimated mortality of 18.6 animals per year is assumed to be human-caused and comments that this may be somewhat positively biased (*i.e.,* a slight overestimate) given that some calf mortality is likely not human-caused. Although the draft SAR acknowledges this is likely a ''slight overestimate,'' its conclusion that all mortality is human-caused is not supported by Sharp *et al.* (2019). The draft SAR ignores the underlying data that of 124 whales examined, 42 percent were confirmed to be anthropogenic (26 due to vessel strikes, 26 due to entanglement), and 58 percent were due to natural or unknown cause (18 neonates died of natural causes, while 54 died of unknown causes). With natural causes constituting a total of 14.5 percent of all examined individuals and 25 percent of those incidents where cause was confirmed, it is not a ''slight overestimate'' and the best available scientific information does not support attributing all mortalities of unknown cause to human activity. MLA reiterates that the SAR must be revised to accurately reflect the best available science.

Response: NMFS disagrees with the assertion that Sharp *et al.* (2019) does not support the assignment of all estimated mortality to human causes. Only 6 deaths of the 124 (2 percent) documented between 1970 and 2018 were attributed to natural causes, and all 6 were calves. For one calf, shark predation was implicated; the other natural deaths were determined to have been stillbirth, dystocia, or malnutrition. Conversely, 100 percent of all examined, non-calf carcasses for which cause of death could be established were determined to have died from either entanglement or vessel collision. Cause of death could not be verified for the remaining carcasses due to either decomposition or logistical constraints, such as distance from shore or poor field conditions. While it is possible that some of these unexamined deaths were due to natural causes, existing evidence indicates right whales rarely die of natural causes. Also see response to comment 39.

Comment 41: MLA states that the report by Kenney (2018) is fundamentally flawed and should not be cited in the SAR. The draft SAR cites Kenney (2018) to support the statement that ''[p]rojection models suggest that the [maximum net productivity rate] could be 4 percent per year if female survival was the highest recorded over the time series from Pace *et al.* (2017).''

Response: The Kenney (2018) reference is a relevant, peer-reviewed study that helps provide context for the impacts of fishery-related mortality on the right whale population. The study does account for other mortality, removing only confirmed fishery-related deaths. Several scenarios are provided with varying levels of hypothetical entanglement mortality rates corresponding to degrees of compliance with MMPA regulations. While the paper presents a very simple representation of complex processes, the model parameters are reasonable and the results are valid.

Gray Seal Western North Atlantic

Comment 42: The Commission requests improved reporting of serious injury data for gray seals. Human-caused serious injury data are reported by source within the SARs, including both observations and extrapolations, if possible. Summaries of observations of human-caused injuries may include some uncertainty of the specific source, but the Commission believes these should still be included in the total M/SI summaries reported in the Status of the Stock section relative to PBR level.

The Commission is concerned that numerous observations of potentially serious injuries of gray seals are not being accounted for in the SAR. Based on unmanned aerial surveys of gray seals hauled out on shore, Martins *et al.* (2019) reported the minimum total number of entangled gray seals could range from 192 to 857 (or 0.83 percent to 3.7 percent of the population in U.S. Atlantic waters). It appears that these seriously injured animals are not being counted in either the commercial fisheries observer M/SI data or the stranding data. Zero serious injuries were reported for 2014–2018 in the commercial fisheries observer data (for both gillnet and trawl fisheries in which mortality is known to occur), and only mortalities are being reported in the human-interaction stranding table. Further, because no serious injuries are reported in fisheries observer data, these injured animals are not accounted for in the extrapolated M/SI estimates either.

The Commission recommends that NMFS ensure that these observations of injured seals are being accurately quantified and included in the SAR, consistent with the agency's 2012 guidelines on injury determinations (including consultation with staff from other Science Centers). The Commission also believes NMFS should continue to collaborate with the Northwest Atlantic Seal Research Consortium, Northeast Fisheries Observer Program, and regional stranding responders on efforts to better photo-document and identify injured and dead seals.

Response: NMFS is actively collaborating on this issue both internally and externally with the Northwest Atlantic Seal Research Consortium. NMFS plans to address how to better document the number of animals living with fisheries entanglements in order to account for them in the SAR, via a standardized system for data collection and entry into the National Stranding Database. The Northeast Fisheries Science Center, in partnership with other organizations, has also submitted a proposal to utilize artificial intelligence to identify specific individuals with entanglements from photographs, which is necessary to avoid double reporting of animals that may live with serious entanglements for several years.

Humpback Whale, Gulf of Maine

Comment 43: The Coalition appreciates the inclusion of cryptic mortality in this analysis, which appropriately elevates the stock to strategic as a result. The Coalition reiterates their comments from last year that the distribution map, while based on NOAA survey data, does not accurately depict the distribution of humpback whales, particularly in the near shore mid-Atlantic areas.

Response: There is a technical error with the Gulf of Maine humpback whale SAR and, as a result, this report has not been finalized. An updated draft report will be published in a subsequent SAR cycle.

Bryde's Whale, Gulf of Mexico Stock

Comment 44: The Coalition appreciates the extensive updates to the Gulf of Mexico Bryde's whale SAR and reminds NMFS that, as an ESA-listed species, the SAR for these whales should be updated every year. The Coalition also reiterates their introductory comments on the general timing of review and comment for the 2020 SARs and the substantial delay in including new information, as it is now known that these whales have been designated as a new species: Rice's whales. The Coalition requests that this new designation be recognized and the 2021 SAR updated accordingly.

Response: Section 117 of the MMPA requires NMFS to review annually, and update as necessary with any new information, SARs for strategic stocks, which would include stocks of ESA-listed species. NMFS will review the Bryde's whale SAR annually to ensure

that applicable updates are incorporated.

The 2021 SARs were drafted in fall of 2020, prior to the publication of the new species recommendation, and the Gulf of Mexico Bryde's whale SAR is not being updated in the 2021 cycle. In order to change the name of the species listed under the ESA, NMFS must update the common and scientific name of this species in the Code of Federal Regulations (CFR; see 50 CFR 224.101) by publishing a technical correction in the **Federal Register** (FR), a process that is currently underway. After the CFR has been updated, we will make the name change in the SAR. Prior to initiating this technical correction, NMFS awaited notification from the Taxonomy Committee of the Society for Marine Mammalogy that they had reviewed the new publication recommending recognition of the Bryde's whales in the Gulf of Mexico as a different species, and that they agreed with the findings and would place the new species on the accepted list of taxonomic names. NMFS received that notification on March 4, 2021. Importantly, the name of the species does not affect the protections it receives under the ESA or the MMPA.

Comments on Pacific Issues

Hawaiian Monk Seal

Comment 45: The Coalition states that the Harting *et al.* (2020) analysis provides important information to guide recovery planning by comparing the impact of multiple threats, and should be cited. Their analysis demonstrates that anthropogenic causes of death of Hawaiian monk seals have a larger impact than either natural or disease causes of death. The Coalition also requests that the recent decision by NMFS that the two monk seals found dead off Kauai in late 2020 likely drowned in lay nets be included in the SAR.

Response: Since these human-caused mortalities are outside the time period for the final 2020 SAR (2014–2018), Harting *et al.* (2020) will be cited in the draft 2021 SAR. Human-caused deaths that occurred in 2020 will be reported in the 2022 SAR.

Bottlenose Dolphin

Comment 46: The Coalition suggests there are several studies about bottlenose dolphin population abundance and health that should be included in the SARs. First, Van Cise *et al.* (in press) observed a decline in abundance in three out of four stocks and lower-than-expected survival rates in all stocks. For these small populations that experience concentrated anthropogenic disturbances, the authors recommended closely monitoring trends in abundance. Second, Stack *et al.* (2019) encouraged the use of bent dorsal fin observations as an indicator of population health for odontocetes. In the case of 164 bottlenose dolphins sighted during the study, none included a bent dorsal fin. The study noted that one bottlenose dolphin with a bent dorsal fin in Hawaii was reported in Alves *et al.* (2018). The Coalition encourages the SARs for these species to include an account of sightings of bent dorsal fins. Third, in a study of coastal waters and marine debris, bottlenose dolphins had the largest area of interaction risk out of all odontocete species (Currie *et al.* 2017). The SARs should include this study as a high-concern threat to bottlenose dolphin habitat.

Response: NMFS is aware of the new abundance estimates for bottlenose dolphins of the Hawaiian Islands Stock Complex presented in Van Cise *et al.* (in press). These estimates will be included in the 2022 draft SARs along with appropriate caveats about the potential influence of sampling variability and bias on the estimates and associated trends. We appreciate the work done by Stack *et al.* (2019), although we interpreted their conclusions as calling for a consideration of the impacts of bent dorsal fins on population health given the potential for long-term effects on individuals, as opposed to suggesting that bent dorsal fins should be used as an indicator of population health. As the authors note, bent dorsal fins are also extremely rare, which makes them less reliable as a measure of population health compared to an attribute such as body or skin condition that could be readily measured across individuals. That said, bent dorsal fins can be indicators of impacts such as fishery interactions. When bent dorsal fin observations are made and linked to human-caused injuries, these could be cited in the SARs of relevant species, as is currently done with other information that provides evidence of potential threats. In that respect, we agree that the threat posed by marine debris described in Currie *et al.* (2017) should be considered for inclusion in the SARs of relevant species.

Killer Whale, Southern Resident Stock

Comment 47: The Coalition reiterates previous comments that the change in return timing and overall use of core summer habitat complicates the established census schedule that the SAR relies on. The Coalition requests that NMFS use the most recent population estimate for Southern Resident killer whales (SRKW) and urges NMFS to include the most recent full count from the Center for Whale Research in the SAR, regardless of the date that count was reached. The Coalition asks that NMFS clearly state the decline observed following the ''peak census count of 99 animals in 1995,'' with average decrease per year, and specifically for the time period included in this SAR. Recent Population Viability Assessments completed in both the U.S. and Canada should be used to describe the current population trend as well as future outlook.

Response: NMFS has helped support the Center for Whale Research's annual Southern Resident killer whales census since 2004. The census technically ends on 1 July of each year (that date continues to be used in order to maintain comparability to prior years). We note that that Center for Whale Research does not provide their 1 July results until 1 October of that year, hence they have the benefit of two additional months, in particular September (for which SRKW still have a relatively high occurrence rate in inland waters), to confirm if animals are missing or assess the survivability of calves. In recent years NMFS has been providing additional support to the Center for Whale Research for surveys outside inland waters to allow them to complete the census by 1 July. As well, in recent years DFO has been working at the west entrance to the Strait of Juan de Fuca from mid-July to mid-August and has provided the Center for Whale Research with photo-identifications from their fairly frequent encounters. However, given that mortalities are relatively rare events (*e.g.,* 4 mortalities in 2019, or approximately one every 3 months), a delay of a month or two in the Center for Whale Research's ability to complete the census only fractionally raises the likelihood that a mortality that occurred after 1 July would be inappropriately ''assigned'' to the prior year census.

Section 117(2) of the MMPA specifies that SARs shall include information on the current population trend. The Population Viability Assessments for SRKW are only projections of the population size, and reporting this information herein has no statutory requirement associated with the SAR and is not included. Language on the population's annual rate of decline following the peak census count in 1995 is included in the SAR, along with the current census value. In addition, Figure 2 displays the population census since 1974, including how the population has increased and decreased in size

following the peak census in 1995. Originally, the caption of Figure 2 provided the citation to Center for Whale Research 2019. However, given the Coalition's comment, we have corrected this citation to be Center for Whale Research 2020, which provides annual census values since 1974 from which specific annual changes in population abundance can be easily calculated if desired.

Comment 48: The Coalition notes that growth rates and productivity in different Resident killer whale populations may be affected by variability in diet, environmental conditions, and habitat range. The Coalition points out that Alaskan Resident killer whales consume Chinook salmon, similar to Northern Resident killer whales (NRKW) and SRKW but appear to have a more diverse diet and benefit from larger and healthier salmon runs. The maximum net productivity rate for NRKW has been updated and is now estimated to be 2.9 percent. The Coalition recommends using the same rate for SRKW, which yields a PBR of 0.11 (1 animal every 9 years) for a population level of 73 whales, as included in this SAR.

Response: NMFS raised this issue with the Pacific SRG in 2020. The Pacific SRG recommended the continued use of Rmax = 0.035 until a better estimate is available for review. We agree with this assessment and will continue to use this Rmax, reviewing it when new information is available.

Humpback Whale, California/Oregon/Washington Stock

Comment 49: The Coalition urges NMFS to revise the CA/OR/WA stock to reflect that the Central America distinct population segment (DPS) is a demographically independent population (DIP) separate from the Mexico DPS and to provide abundance estimates for both.

The Coalition requests the inclusion of the record of two dead humpback whales caught in Pacific whiting midwater trawl nets in separate incidents in July 2020. Seen only on electronic monitoring (EM), the whales could neither be identified to DPS nor necropsied to determine cause of death. The Coalition notes that as EM programs continue to expand, and more vessels opt to use EM instead of observers, it will be increasingly difficult to track marine mammal interactions as cameras are not currently designed to monitor marine mammal interactions. This will in turn decrease the amount of data on marine mammal interactions with commercial fisheries and increase uncertainty in M/SI estimates in several marine mammal stock assessments. The Coalition recommends NMFS improve the quantity and quality of information collected on marine mammal interactions.

Response: NMFS appreciates this recommendation regarding designating humpback whale stocks. In late 2019, NMFS finalized a new Policy Directive: Reviewing and Designating Stocks and Issuing Stock Assessment Reports under the Marine Mammal Protection Act (NMFS 2019). This directive established that DIP delineation and stock designation are separate processes. DIP delineation is the process of interpreting the scientific lines of evidence supporting whether groups of animals are demographically independent, including determining the geographic range of the groups. DIP delineation occurs outside the SAR process, and is described in Martien *et al.* (2019). Stock designation is the process of officially classifying a stock as a management unit that will then be described and assessed in SARs and considers whether individual DIPs can be effectively managed as stocks. In light of the 2016 ESA humpback whale DPS listings, the MMPA humpback whale stock designations are currently being re-evaluated according to the process laid out in NMFS (2019). NMFS is reviewing the best available science on humpback whale population structure in the Pacific and evaluating the lines of evidence to, where possible, delineate humpback whale DIPs as guided by Martien *et al.* (2019). This review and evaluation is currently underway and following its completion, we will follow the process to revise stock designations following NMFS (2019) as resources allow.

Both the humpback whale incidents referred to in the comment were outside the time frame of this SAR. Regarding EM technologies, NMFS believes these can provide valuable supplementary data in addition to traditional fisheries observers for collecting data on fishing effort and catch (landings and discards), including bycatch of protected species. While we have made significant strides in assessing the technology and potential applications of EM, there are continuing policy and data-related challenges that come with new technologies. These include how to process and store the enormous amount of electronic data, enforcement of compliance issues, privacy concerns of fishery participants, costs, and image processing. As research and development efforts continue, we are actively working to include protected species in those efforts. In time, we expect to see EM technologies available for wider applications, including select fisheries for monitoring bycatch of protected species.

False Killer Whale, Hawaiian Island Stock Complex

Comment 50: HLA appreciates that NMFS has updated the False Killer whale SAR to incorporate the results of the line transect survey that occurred in 2017, as well as NMFS' associated modeling work. For future surveys, HLA requests that the results be processed and reported in the SAR more promptly. HLA comments that it is not consistent with the MMPA, or otherwise acceptable, to update a SAR with key information four years after the data has been gathered. HLA believes the results presented in the draft SAR, which reflect the best available scientific information, demonstrate that the deep-set fishery's M/SI rate for the Hawaii Pelagic False Killer whale Stock (Pelagic Stock) is far below the stock's PBR. Specifically, the deep-set fishery's M/SI rate in the U.S. EEZ (6.5) is less than half of the PBR for the Pelagic Stock in the EEZ (16), and the fishery's overall Pelagic Stock M/SI rate (35.3 [combining inside and outside the EEZ]) is less than 15 percent of NMFS estimated PBR for the central Pacific (259). These results confirm the positions HLA has taken since the False Killer whale Take Reduction Team formed in 2009—*i.e.,* that NMFS has consistently underestimated the abundance of the Pelagic Stock and that the deep-set fishery's M/SI rate does not exceed, and has never exceeded, the PBR for that stock. HLA comments that it presented a detailed statistical analysis performed by Dr. Ray Hilborn showing that NMFS had substantially underestimated the population size of the Pelagic Stock in the Hawaii EEZ. At that time, NMFS estimated the EEZ stock size to be 484 whales. Dr. Hilborn's analysis concluded that a more accurate abundance estimate was 2,066 whales in the EEZ. After HLA presented those results, HLA believes NMFS wrongly criticized and discarded Dr. Hilborn's analysis.

HLA comments that NMFS current estimate for the Pelagic Stock in the EEZ is 2,086 whales (only 20 more than Dr. Hilborn estimated in 2009). HLA comments that the best available science, as reported in the draft SAR, shows that the population size of the Pelagic Stock in the EEZ has consistently been approximately 2,100 animals going back to 2002. Specifically, the draft SAR, based on Bradford *et al.* (2020), estimates that the stock numbered 2,144 animals in 2010

and 2,122 animals in 2002. This demonstrates that the Pelagic Stock has never been ''strategic'' because the deep-set fishery's M/SI rate has never exceeded a PBR based on those abundances. This also shows that there was no basis, as HLA argued in 2009, to include the Pelagic Stock within the scope of the False Killer whale Take Reduction Team. Finally, HLA believes the best available science also shows that the Pelagic Stock is either increasing or, at worst, remaining stable. If NMFS' pre-2010 estimate of 484 whales for the Pelagic Stock in the EEZ is to be believed, then the stock has increased in size dramatically over the ensuing years. Alternatively, based on the current best available science (Bradford *et al.* 2020), the stock has remained stable at a high abundance (of approximately 2,100 whales) within the Hawaii EEZ since at least 2002. Either way, HLA believes there is no evidence that the Hawaii-based longline fisheries are having any noticeable impact on the stock.

Response: NMFS agrees that the timely publication of results that inform SARs is important. Surveys were completed at the end of 2017, and the collected data were quality-checked and verified into 2018. New data protocols designed to improve abundance estimates for this species had to be integrated with existing line-transect methodology and updated analysis approaches to obtain the most robust estimates of abundance. After undergoing peer review, the final results were published in 2020, with the time between data collection and publication consistent with other studies using new approaches to generate estimates of abundance.

False killer whale assessments are complex. We have learned a lot about false killer whale social structure and behavior over the past 10–15 years that has significantly changed the way we collect and analyze survey data for this species. While we have much greater confidence in our 2002, 2010, and 2017 estimates now than we did when the 2002 or 2010 estimates were originally formulated, the older estimates were the best available estimates at the time they were published and used in the SARs. We no longer refer to those estimates in the SAR because they are no longer the best available. To refer to them now as rationale for arguing the stock has increased is inappropriate. The MMPA calls for using the best available scientific data available at the time that the assessments are to be completed. PBR is designed to deal with great uncertainty and is inherently precautionary. Although it is coincidental that the Hilborn 2009 analysis produced an abundance estimate that is close to our current estimate, our assessment of that analysis has not changed. There were documented problems with the Hilborn analysis, and it used what are now severely outdated data and parameter estimates, such that it is inappropriate to compare the outdated Hilborn 2009 estimate with our current estimate representing years of targeted improvements in data collection, analytical approach, g(0) estimation, etc.

With regard to comparing the current PBR to fishery mortality, we are clear within the SAR and in all other communications about our pelagic stock abundance estimates that the full central Pacific estimate provided in Bradford *et al.* (2020) and in the SAR represents more than one stock of false killer whales. The Palmyra stock, Hawaii pelagic stock, and any Eastern Pacific stocks are all also partially included here. Since we do not presently have high-seas boundaries for any of these stocks, we are not able to partition the full central Pacific estimate to the Hawaii pelagic stock, and, therefore, cannot meaningfully compare the full Hawaii pelagic stock abundance and PBR with fishing mortality.

Comment 51: HLA comments that the draft 2020 SAR assigns a recovery factor of 0.5 to the Hawaii pelagic stock, which is the value typically assigned to depleted or threatened stocks or stocks of unknown status with a mortality estimate CV of 0.3 or less. However, the Hawaii pelagic stock is not depleted or threatened, nor is its status unknown. This status should be accurately reflected with a recovery factor that is greater than 0.5 (*i.e.,* closer to 1.0 than to 0.5).

Response: A recovery factor of 0.5 is appropriate for the Hawaii pelagic stock. There are no estimates of population trend for this stock, and the model used to produce the new 2002, 2010, and 2017 could not accommodate a trend term given the sparse dataset. Stable or increasing levels of bycatch and depredation may be driven by a number of factors, including increasing overlap in the occurrence of false killer whales and fishing activity, learning by whales to approach fishing boats, increasing false killer whale population, or changes in the fishery that allow for higher rates of depredation or observed bycatch.

Comment 52: HLA comments there have been no Hawaii-based deep-set longline fishery interactions with the Main Hawaiian Islands (MHI) insular false killer whale stock and comments that the draft SAR incorrectly attributes M/SI to the deep-set fishery in 2017 and in 2018. HLA requests that, if NMFS nevertheless proceeds to attribute M/SI to the deep-set fishery (which HLA strongly disagrees with), then HLA requests the draft SAR should at a minimum state that there are no confirmed deep-set fishery interactions with the MHI insular stock, and that no deep-set fishery interactions with the MHI insular stock have occurred in the very limited area where longline effort might overlap with the assumed range for the stock.

Response: NMFS has addressed this concern in previous responses to comments on the SARs. NMFS' Observer Program does not observe every deep-set trip. With ~20 percent coverage, some statistical extrapolation/approximation of what is observed is required. False killer whale takes are relatively rare. The rarity of observed takes, together with the sampling design mean that the lack of observation does not equate to the lack of actual interactions. We agree that we can more explicitly state that no confirmed MHI insular false killer whales have been observed as taken in this fishery, though this needs to be balanced by the fact that very few of the observed takes are identified to stock due to the lack of tissue samples or adequate photographs. NMFS is not attributing interactions that occur outside of the MHI insular stock area to the MHI insular stock. We are prorating the estimated portion of the take to account for fishing effort that occurs within the MHI insular stock range and based on the relative density of the false killer whale stocks in this area. In reality, if an MHI insular false killer whale were taken by the fishery, we would very likely be underestimating the impact on this stock given our current proration method.

Comment 53: HLA notes that the draft SAR estimates the MHI insular stock abundance to be 167 animals, based upon Bradford *et al.* (2018), which found that the population size of the MHI insular stock in certain study areas has consistently ranged between 144 and 187 animals over a 16-year period. HLA comments that the draft SAR's reported abundance estimate of 167 animals underestimates the MHI insular stock's abundance, perhaps to a very significant degree. HLA comments that it is unscientific and contrary to the MMPA for NMFS to report the estimated abundance for only a portion of the MHI insular stock. HLA notes that the MMPA requires the SAR to ''describe the geographic range of the affected stock'' and to provide minimum population estimates for ''such stock'' (not a ''portion of such stock''). HLA

states in its comments that NMFS has made no attempt to estimate the abundance of the MHI insular stock across its range or to apply ''appropriate correction factors'' to do so. HLA notes that the draft SAR is therefore legally deficient and must be corrected.

If NMFS nonetheless retains the MHI insular stock abundance estimate of 167 animals, then HLA believes that number should be considered the ''minimum population estimate.'' HLA notes that as Bradford *et al.* (2018) acknowledges, the estimate of 167 animals is an underestimate, so there is no need to apply an additional reduction factor to this number for purposes of reporting the ''minimum population estimate'' because NMFS already has a scientifically published ''reasonable assurance that the stock size is equal to or greater than'' 167 animals. HLA comments that to report an even lower ''minimum population estimate'' is arbitrary and contrary to the MMPA.

Finally, HLA believes should NMFS retain the MHI insular stock population estimate of 167 animals with no additional information about the actual population size, it must, consistent with its obligation to report the best available scientific information, disclose what specific portion of the MHI insular stock's range was surveyed in the Bradford *et al.* (2018) study. HLA believes if NMFS is going to report an abundance estimate for only a portion of an MMPA stock's range, then at the very minimum it must disclose to the public what portion of the range is at issue.

Response: The second excerpt from Bradford *et al.* (2018) was incomplete. The remainder of the quoted paragraph is: ''However, movement analyses of 2 of the 3 social clusters have shown that individuals satellite-tagged by CRC [Cascadia Research Collective] on the leeward sides of the MHI regularly use both leeward and windward waters throughout the chain (Baird *et al.* 2010, 2012), which suggests there are unlikely to be individuals in the population that never use the predominantly leeward sampling areas [that were clearly identified relative to the stock range in Figure 1 of the paper]. Therefore, it is likely that all individuals in the population have been exposed to sampling efforts at some point during the study period, although not necessarily in each year.'' In general, this paper appropriately acknowledges that unavoidable sampling biases led to some degree of underestimation in the annual abundance estimates, but that all supporting evidence indicates the population is small. Thus, there is no basis to suggest that this underestimation is substantial. NMFS has, and will continue to work towards understanding and addressing the availability issues discussed at length in Bradford *et al.* (2018), though we do not believe the underestimation is equal in all years or that it is substantial in any year. We will continue to use the point estimates and CV provided there to compute an Nmin.

Comment 54: WPRFMC comments that in the draft 2020 SAR, NMFS uses only the most recent abundance estimate to calculate the PBR. WPRFMC recommends that using a tiered approach for calculating PBR based on data availability would allow for the use of all available abundance estimates to estimate the minimum population estimate (Nmin) and recovery factor, and reduce the uncertainty in the PBR estimates. WPRFMC therefore requests that NMFS include all available abundance estimates for the pelagic false killer whale stock using the approach developed by Brandon *et al.* (2017).

Response: NMFS appreciates the request for more expediency in generating false killer whale abundance estimates and reporting them in the SARs. We understand the importance of these estimates and their bearing on management, which underscores our commitment to ensure our results are as robust and reliable as possible. Please see our response to comment 50.

Regarding the tiered PBR approach, the MMPA calls for using the best available scientific data available at the time that the assessments are to be completed. The NMFS Guidelines for Assessing Marine Mammal Stock (GAMMS 2016), provide guidance on the calculation of Nmin to the 20th percentile of a log-normal distribution. This approach is designed to deal with great uncertainty and is inherently precautionary.

North Pacific Gray Whales

Comment 55: The Makah Tribe notes that the draft SAR compounds contextual ambiguity by using the name Western Breeding Stock (WBS) to identify the ''third unnamed stock'' in the description of the International Whaling Commission (IWC) Scientific Committee's stock structure hypothesis 4a. They recommend that NMFS either name the third implied stock based on its feeding and wintering grounds, *e.g.,* Sakhalin Eastern Breeding Stock which will distinguish it from the WBS and Eastern Breeding Stock (EBS), or use the same phrase as the IWC Scientific Committee: ''WFG (Western Feeding Group) whales that interbreed largely with each other while migrating to the Mexican wintering ground'' (IWC 2020b).

Response: NMFS has aligned the stock hypothesis language used in the IWC stock structure document (IWC 2020b) with that appearing in both the Eastern North Pacific (ENP) and Western North Pacific (WNP) gray whale SARs. This should eliminate the previously confounding reference to the WBS for the implied third breeding stock. The unnamed third breeding stock referenced by the IWC is now referred to as ''WFG (Western Feeding Group) whales that interbreed largely with each other while migrating to the Mexico wintering ground.''

Comment 56: The Makah Tribe comments that the new abundance estimate for the Pacific Coast Feeding Group (PCFG) was completed in late 2019 and should be included in the 2020 SAR in the section on Population Size, Potential Biological Removal, and other appropriate sections to reflect current information (Calambokidis *et al.* 2019). The SAR should also include the recently published abundance estimate for the ENP stock based on the 2019–20 survey (Stewart and Weller 2021). Also, the Makah Tribe recommends removing the description of the stranded whales as emaciated in the description of the Unusual Mortality Event (UME) in the Population Size section.

Response: NMFS appreciates reference to new documents that became available during the public comment period for the draft 2020 SARs. New abundance estimates for ENP and PCFG whales will be included the next time the ENP SAR is revised. This will allow for thorough peer review by the SRG and adequate public comment. Language has been changed in the final 2020 SAR to better reflect the variable body conditions of stranded whales during the UME. Figures that pertain to the UME have been removed from the SAR and the reader is now pointed to the UME website, which includes periodic updates to the UME status.

Comment 57: The Makah Tribe recommends the first sentence of the Subsistence/Native Harvest Information section be modified to remove the geographic limitation to the Bering Sea. Furthermore, the Makah Tribe requests that the sentence should recognize that gray whales were once hunted in Canada (Monks *et al.* 2001). Additionally, in the new text describing NMFS' proposed waiver, the Makah Tribe recommends two changes. First, in the reference to three annual strikes, the SAR should explain that this is the maximum number of strikes allowed under the proposed regulations, *e.g.,*

''based on the maximum allowed 3 strikes annually.'' Second, the description of the post-hearing comment period should reflect that it ended in March 2020, *e.g.,* ''NMFS requested public comment.'' Also, the description of the IWC's approval of a gray whale catch limit should be revised to reflect current terminology, e.g, replacing ''quota'' with ''catch limit,'' and should reflect changes to the catch limit made in 2018.

Response: NMFS has included new language in the final 2020 SAR to incorporate these suggestions.

Comment 58: The draft SAR refers to unpublished reports that have since been published in peer-reviewed journals. The Makah Tribe recommends that the following replacement citations for unpublished reports be used where applicable: Lang *et al.* (2011b) should be updated to Lang *et al.* (2014) and Mate *et al.* (2010) should be updated to Lagerquist *et al.* (2019).

Response: These references have been updated in the final 2020 SAR.

Comment 59: Please see the Makah Tribe's recommended changes to IWC stock structure hypotheses in the draft SAR for the ENP stock, as the draft WNP SAR incorporates identical text.

Response: See response to comment 57.

Comment 60: The tribe comments that the draft SAR updates text regarding the estimated probabilities of a Makah hunt taking a WNP gray whale to reflect the conclusions of Moore and Weller (2018). However, in making the update, the draft SAR fails to carry forward an explanation of the probabilities that is helpful to laypeople reading the SAR and makes clear that the estimated probability of such a take is very low. The Makah Tribe recommends that an updated version of that explanatory sentence (''This corresponds to an expectation of greater than 1 WNP whale strike in one of every 83 to 167 years''), which is stricken in the raft SAR, be included in the revision. NMFS also needs to correct the 95 percent Bayesian Credible Interval (CRI) for the probability for a 10-year hunt to ''(95 percent CRI 0.030–0.093).'' Because the same text is used in the draft ENP SAR, the changes above should be made in revising that SAR as well.

Response: NMFS has added language to reflect statements from the proposed rule (84 FR 13604; April 5, 2019) that provides details on the WNP risk assessment by Moore and Weller (2018).

Comment 61: The Status of Stock section of the draft SAR begins with the assertion that ''[t]he WNP stock is listed as 'Endangered' under the U.S. Endangered Species Act of 1973 (ESA) and is therefore also considered 'strategic' and 'depleted' under the MMPA.'' As with previous SARs for the WNP stock, no explanation of the listing status is provided, but the draft SAR does note an ongoing 5-year Status Review initiated by NMFS in 2018. The Tribe believes NMFS never addresses the crux of the issue, *i.e.,* the agency's description of the WNP stock in the 1994 ESA delisting decision as geographically and reproductively isolated from the ENP stock is fundamentally inconsistent with the draft SAR's classification of whales migrating from Sakhalin to Mexico as part of the same WNP stock and, therefore, ''Endangered.''

In the draft SAR, intermittent observations of gray whales in Asian waters are cited as evidence of continued migration to an Asian breeding ground. Further, Cooke *et al.* (2019) found that up to 20 percent of WNP whales migrate to breeding grounds in Asian waters, providing support for their conclusion that ''it is likely that a western breeding population that migrates through Asian waters still exists.'' At the same time, the IWC Scientific Committee has developed stock structure hypotheses where in the most plausible hypotheses the WBS, which in Makah's view corresponds to the WNP stock described in the ENP stock's delisting documents, has either been extirpated (3a and 4a) or is extant but exists solely in Asian waters (5a). The same hypotheses postulate that whales that feed at Sakhalin and migrate to North America are either the WFG, which interbreeds with other whales of the EBS (3a and 5a) or breeds largely with other WFG whales while migrating to Mexico (4a). NMFS has never provided a rational explanation for its treatment of WFG whales, *i.e.,* those Sakhalin whales that migrate to North America, as equivalent to the WBS, which as described by the IWC matches the agency's 1994 description of the geographically isolated, ''Endangered'' WNP stock. Indeed, the agency's incorrect use of ''WBS'' for the unnamed, implied third breeding stock, as discussed above, appears related to this lack of clarity in the draft SAR. Absent an explanation in the SAR, NMFS' assertion that the WNP stock described in the draft SAR is ''Endangered'' is untenable and the Status of Stock should be changed to ''unknown'' until NMFS makes a formal determination of the status of WFG whales.

The Tribe has commented at length on this issue in previous draft SARs (2014 and 2018) and believes NMFS' response does not explain how, if at all, the agency's view of stock structure corresponds to the stock structure hypotheses of the Scientific Committee.

Response: We acknowledge that the stock structure of North Pacific gray whales is an area of active investigation, internationally and domestically, as evidenced by the IWC's Scientific Committee currently recognizing three 'high plausibility' stock structure hypotheses for WNP gray whales (IWC 2020). Consistent with our responses to related comments from the Makah on the 2018 SAR, we have relied on the best available information to update the ''Stock Definition and Geographic Range'' information in the final SAR. Also, NMFS has convened a Status Review Team to evaluate this information and the ESA status of WNP gray whales (83 FR 4032; January 29, 2018), including the delineation of any distinct population segment (DPS). Results from this evaluation will be incorporated as appropriate in future updates of the North Pacific gray whale SARs.

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Dated: July 19, 2021.

Evan Howell,

Director, Office of Science and Technology, National Marine Fisheries Service.

[FR Doc. 2021–15701 Filed 7–22–21; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the procurement list.

SUMMARY: The Committee is proposing to delete product(s) and service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Comments must be received on or before:* August 22, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following product(s) and service(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
7510–01–600–7582—Monthly Wall Calendar, Dated 2021, Jan–Dec, 8½″ x 11″
7510–01–600–7630—Wall Calendar, Dated 2021, Wire Bound w/Hanger, 12″ x 17″
7510–01–600–7575—Wall Calendar, Dated 2021, Wire Bound w/hanger, 15.5″ x 22″
7510–01–682–8098—Wall Calendar, Recycled, Dated 2021, Vertical, 3 Months, 12¼″ x 26″
7530–01–600–7617—Weekly Planner Book, Dated 2021, 5″ x 8″, Black
7530–01–600–7590—Daily Desk Planner, Dated 2021, Wire bound, Non-refillable, Black Cover
7530–01–600–7597—Monthly Desk Planner, Dated 2021, Wire Bound, Non-refillable, Black Cover
7530–01–600–7601—Weekly Desk Planner, Dated 2021, Wire Bound, Non-refillable, Black Cover
7510–01–682–8110—Professional Planner, Dated 2021, Recycled, Weekly, Black, 8½″ x 11″
7510–01–682–8091—Monthly Planner, Recycled, Dated 2021, 14-month, 6⅞″ x 8¾″
Designated Source of Supply: Chicago Lighthouse Industries, Chicago, IL
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s): 7510–01–600–8027—Dated 2021 12-Month 2-Sided Laminated Wall Planner, 24″ x 37″
Designated Source of Supply: Chicago Lighthouse Industries, Chicago, IL
Contracting Activity: GSA/FAS FURNITURE SYSTEMS MGT DIV, PHILADELPHIA, PA

NSN(s)—Product Name(s): 7520–01–622–7156—Portable Desktop Clipboard with Calculator, 10″ W x 2⅗″ D x 16″ H, Army Green
Designated Source of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):
7520–01–587–9633—Pen, Ballpoint, Retractable, 3 Pack, Black, Medium Point
7520–01–587–9650—Pen, Ballpoint, Retractable, Hybrid Ink, 6 Pack, Assorted, Medium Point
Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s): 7510–01–579–9322—Binder, Removable Slant-D Rings, 100% Recyclable, Turned Edge, Dark Green, 3″ Capacity, Letter
Designated Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: STRATEGIC ACQUISITION CENTER, FREDERICKSBURG, VA

NSN(s)—Product Name(s): 7510–01–579–9322—Binder, Removable Slant-D Rings, 100% Recyclable, Turned Edge, Dark Green, 3″ Capacity, Letter
Designated Source of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s): 7930–00–NIB–0720—Dust Remover, Compressed Gas, 10 oz.
Mandatory Source of Supply: The Lighthouse for the Blind, St. Louis, MO
Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

NSN(s)—Product Name(s):
7520–01–484–5259—Pen, Ball Point, Retractable, Ergonomic, MD Executive Grip, Burgundy Barrel, Black Ink, Medium Point
7520–01–484–5255—Pen, Ball Point, Retractable, Ergonomic, MD Ergo Grip, Burgundy Barrel, Black Ink, Medium Point
Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

NSN(s)—Product Name(s):
8465–01–519–6132—Load Lifter Attachment Strap, MOLLE Components, Desert Camouflage
8465–01–524–7241—Load Lifter Attachment Strap, MOLLE Components, Universal Camouflage
8465–01–580–1666—Load Lifter Attachment Strap, MOLLE Components, OEFCP
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s): 8465–01–580–1666—Load Lifter Attachment Strap, MOLLE Components, OEFCP
Contracting Activity: W6QK ACC-APG NATICK, NATICK, MA

NSN(s)—Product Name(s): 8455–01–113–0061—Qualification Badge, Basic Expert, U. S. Army
Mandatory Source of Supply: Fontana Resources at Work, Fontana, CA
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

NSN(s)—Product Name(s): 6640–00–165–5778—Kit, Urine Specimen Bottles With Mailers
Designated Source of Supply: Alphapointe, Kansas City, MO
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

Service(s)

Service Type: Sourcing, Warehousing, Assembly and Kitting
Mandatory for: Army National Guard Recruiting and Retention Command, Nashville, TN, Houston Barracks, Nashville, TN
Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI
Contracting Activity: DEPT OF THE ARMY, W7N1 USPFO ACTIVITY TN ARNG

Service Type: Furniture Design and Configuration Services
Mandatory for: Maine National Guard, Augusta, ME, 194 Winthrop Street, Augusta, ME

Designated Source of Supply: Industries for the Blind and Visually Impaired, Inc., West Allis, WI

Contracting Activity: DEPT OF THE ARMY, W7NC USPFO ACTIVITY ME ARNG

Michael R. Jurkowski,

Deputy Director, Business Operations.

[FR Doc. 2021–15737 Filed 7–22–21; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2018–0005]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on Smoke and Carbon Monoxide Alarms

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) requests comments on a proposed extension of approval for an information collection on a survey that will estimate the use of smoke and carbon monoxide alarms in United States households. The Office of Management and Budget (OMB) previously approved the collection of information under OMB Control No. 3041–0180. The current information collection will expire on October 31, 2021. CPSC will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from OMB.

DATES: Submit written or electronic comments on the collection of information by September 21, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2018–0005, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC does not accept comments submitted by electronic mail (email), except through *https://www.regulations.gov* and as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Written Submissions: Submit comments by mail/hand delivery/courier to: Division of the Secretariat, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. Alternatively, as a temporary option during the COVID–19 pandemic, you may email such submissions to: *cpsc-os@cpsc.gov*.

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments received without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov*. Do not submit electronically: Confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* insert Docket No. CPSC–2018–0005 into the ''Search'' box, and follow the prompts. A copy of the proposed survey titled ''SCOA ICR 2021 60-day'' is available at: *http://www.regulations.gov* under Docket No. CPSC–2018–0005, Supporting and Related Material.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Commission is authorized under section 5(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2054(a), to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. Section 5(b) of the CPSA, 15 U.S.C. 2054(b), further provides that the Commission may conduct research, studies, and investigations on the safety of consumer products or test consumer products and develop product safety test methods and testing devices.

In 1992, the CPSC sponsored a national in-home survey to collect information on the number of residential smoke alarms in actual use in homes and to evaluate the operability of the sampled alarms. The results were published in the 1994 report, *Consumer Product Safety Commission Smoke Detector Operability Survey Report on Findings.*[1] Although the survey results were instrumental for many years in developing state and local codes and standards related to smoke alarms, subsequent changes in technology, installation codes, and state/local ordinances in the past 25 years have rendered the information outdated and less effective. Stakeholders' groups for fire loss prevention have identified a need for an updated national survey to increase the installation and maintenance of smoke alarms in the United States. In addition, installations of CO alarms have increased since 1992. Accordingly, CPSC sought to update its data information collection related to smoke and CO alarm use through a new survey, the National Smoke and CO Alarm Survey (SCOA survey).

Although the SCOA survey initially commenced in January 2019, CPSC experienced lower response rates relative to expectations in the administration of the SCOA survey in fielding locations than had been established by the study's approved methodology. To correct for this challenge, and to complete the number of homes surveyed in the contract, CPSC undertook a revised sampling method and contact protocol of participant recruitment. Among the revisions to the methodology, CPSC included a redesign of the recruitment, screening, and in-home survey based on a random walk door-to-door knocking sample methodology. The SCOA survey seeks to collect information from 1,185 households within the United States. The survey will be conducted only through face-to-face, in-home interviews. Following all COVID–19 safety precautions, survey professionals will provide pre-notification door hangers requesting participation in the survey. These households will be recruited, and willing participants will be provided with consent forms, and the survey team will administer questions regarding the residence type, and smoke and CO alarm availability and functionality in the residences. The survey team also will identify, test, and examine several of the alarms in the home, as time permits, and if they are found faulty, provide new alarms or batteries, if requested by the participant. No action will be taken if participants choose not to have the alarm fixed or replaced.

CPSC entered into a contract with Eureka Facts to conduct the SCOA survey through a national in-home survey that would estimate the use and

[1] 1. Charles L. Smith, *Smoke Detector Operability Survey—Report on Findings,* (Bethesda, MD: CPSC, November 1993).

functionality of smoke and CO alarms in households, as well as assess user hazard perceptions regarding such alarms. The purpose of the SCOA survey is to collect data that will assist CPSC with better estimation of the number and types of smoke and CO alarms installed in U.S. households, the proportion of working smoke and CO alarms, the characteristics of residences and residents where the smoke and CO alarms are not operational, perceptions of residents related to the causes of ''false'' alarms or causes of faulty alarms, consumer hazard awareness, and consumer behavior related to alarm use and smoke and CO hazards.

The information collected from the SCOA survey would provide CPSC updated national estimates regarding the use of smoke alarms and CO alarms in households, based on direct observation of alarm installations. The survey also would help CPSC identify the groups that do not have operable smoke alarms and/or CO alarms and understand the reasons why they do not have such alarms. With this information, CPSC would be able to target better its messaging to improve consumer use and awareness regarding the operability of these alarms. In addition, the survey results would help to inform CPSC's recommendations to voluntary standards groups and state/local jurisdictions regarding their codes, standards, and/or regulations on smoke and CO alarms.

B. Burden Hours

We estimate the number of respondents to be 1,185. We estimate the total annual burden hours for respondents to be 1,552 hours, based on the total time required to respond to the invitation, screener, and the actual survey. According to the U.S. Bureau of Labor Statistics, the total compensation for civilian workers in March 2021 was $39.01 per hour (Employer Cost for Employee Compensation, Table 2, *https://www.bls.gov/news.release/ecec.t02.htm*). Therefore, CPSC estimates the cost burden for respondents to be $60,544 ($39.01 per hour × 1,552 hours = $60,543.52). The total cost to the federal government for the contract to design and conduct the revised survey is $562,725.

C. Request for Comments

The CPSC invites comments on these topics:

- Whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- The accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2021–15735 Filed 7–22–21; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Environmental Impact Statement for Army Training Land Retention of State Lands at Kahuku Training Area, Poamoho Training Area, and Makua Military Reservation, Island of O'ahu, Hawai'i

AGENCY: Department of the Army; DoD.

ACTION: Notice of intent.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA) 1969 and the Hawai'i Environmental Policy Act (HEPA), the Department of the Army (Army) is issuing this Notice of Intent to prepare an Environmental Impact Statement (EIS) to address the Army's proposed retention of up to approximately 6,300 acres of land currently leased to the Army by the State of Hawai'i (''State-owned lands'') on the island of O'ahu. Lease agreements between the State of Hawai'i and the Army at each of these three training areas were initiated in 1964 and expire in 2029. State-owned lands includes approximately 1,170 acres at Kahuku Training Area (KTA), approximately 4,370 acres at Poamoho Training Area (Poamoho), and approximately 760 acres at Makua Military Reservation (MMR). Training areas are utilized by Army units and other users such as the Marine Corps and Hawaii Army National Guard. Because the Proposed Action involves State-owned lands, the EIS will be a joint NEPA–HEPA document; therefore, the public scoping processes will run concurrently and will jointly meet NEPA and HEPA requirements. The EIS will evaluate the environmental impacts from implementing the proposed land retention.

DATES: The Army invites public comments on the scope of the EIS during a 40-day public scoping period. Comments must be received by September 1, 2021.

ADDRESSES: Please send written comments to the EIS website at: *https://home.army.mil/hawaii/index.php/OAHUEIS.* Alternatively, comments can be emailed to *usarmy.hawaii.nepa@mail.mil,* or mailed to: O'ahu ATLR EIS Comments, P.O. Box 3444, Honolulu, HI 96801–3444.

FOR FURTHER INFORMATION CONTACT: Please contact Amy Bugala, U.S. Army Garrison-Hawai'i (USAG–HI) Public Affairs Officer, at: (808) 656–3160 or by email to: *usarmy.hawaii.comrel@mail.mil.*

SUPPLEMENTARY INFORMATION: USAG–HI is home to the 25th Infantry Division (ID), and other commands, whose mission is to deploy to conduct decisive actions in support of unified land operations; the Division conducts continuous persistent engagement with regional partners to shape the environment and prevent conflict across the Pacific operational environment. On orders, these units may conduct theater-wide deployment to perform combat operations in support of U.S. Indo-Pacific Command (USINDOPACOM). The 25th ID is based out of Schofield Barracks on the island of O'ahu and trains on a rotational basis at various training areas, including KTA, Poamoho, and MMR.

Located in northeast O'ahu, KTA has been the site of military training since the mid-1950s. Current training activities on State-owned lands at KTA include high-density company-level helicopter training in a tactical environment, large-scale ground maneuver training, and air support training.

Located in the Ko'olau Mountains in north-central O'ahu, the Poamoho Training Area has been the site of military training since 1964 and provides ideal airspace with ravines and deep vegetation vital to realistic helicopter training.

Located in northwest O'ahu, MMR has been a site for military training for nearly 100 years. Tactical training at MMR began in 1941 after the surprise attack on Pearl Harbor and military exercises continue to this day. Current training activities on State-owned lands at MMR include maneuver training, the establishment and use of restricted airspace for unmanned aerial vehicle training, as well as wildfire suppression and security activities.

The purpose of land retention is to secure the long-term military use of

State-owned parcels, for which current leases expire in 2029. The need to retain use of these training lands is to allow the military to continue to meet current and future training and combat readiness requirements on Army-managed lands in Hawai'i.

To understand the environmental consequences of the decisions to be made, the EIS will evaluate the reasonably foreseeable impacts of a range of potential alternatives that meet the purpose of and need for the Proposed Action. Alternatives to be considered include the No Action Alternative, (1) Full Retention, (2) Modified Retention, and (3) Minimum Retention and Access. The Proposed Action does not involve new training, construction, or resource management activities. Under Full Retention, the Army would retain all State-owned lands within each training area. Under Modified Retention, the Army would retain all State-owned lands within each training area except lands on which limited training occurs. Under Limited Retention and Access, the Army would retain the minimum amount of State-owned lands within each training area that is required for USARHAW to continue to meet its current ongoing training requirements. This includes the State-owned lands with the most vital training/support facilities, infrastructure, maneuver land, all U.S. Government-owned utilities, and access to these features. Other reasonable alternatives raised during the scoping process that meet the Army mission, project purpose, and need will also be considered for evaluation in the EIS.

An EIS-level analysis is being undertaken because the land retention action could have potentially significant impacts on environmental and social resource areas including biological resources, cultural resources, hazardous and toxic materials and wastes, socioeconomics, utilities, and human health and safety. The analysis in the EIS will determine the projected level of impact on each resource area.

The Army anticipates permits and authorizations may be required for the Proposed Action, including a lease from the State of Hawai'i Department of Land and Natural Resources (DLNR), National Historic Preservation Act and Hawai'i Historic Preservation Review consultation with the State Historic Preservation Officer, Endangered Species Act Section 7 consultation with the U.S. Fish and Wildlife Service, a Coastal Zone Management consistency determination from the Hawai'i State Office of Planning, and a Conservation District Use Permit applicability determination from the DLNR Office of Conservation and Coastal Lands.

The Draft EIS will be available in the summer of 2022. The Final EIS 2023, ROD spring 2024. The Final EIS and Record of Decision are estimated to be available within three years of this notice.

Native Hawaiian organizations; Federal, State, and local agencies; and the public are invited to be involved in the scoping process for the preparation of this EIS by participating in a scoping meeting and/or submitting written comments. The Army requests assistance with identifying potential alternatives to the Proposed Action to be considered and identification of information and analyses relevant to the Proposed Action. Written comments must be sent within 40 days of publication of the Notice of Intent in the **Federal Register**. In response to the coronavirus (COVID–19) pandemic in the United States and the Center for Disease Control's current recommendations for social distancing and avoiding large public gatherings, the Army may not hold in-person public scoping meetings for this action. In lieu of in-person public scoping meetings, the Army may provide virtual scoping opportunities that will include an online presentation and collaboration tools, as appropriate, and reasonable accommodations for the public to view information and provide oral or written comments subject to COVID–19 limitations. An EIS Scoping Virtual Open House will be held at Leilehua Golf Course (199 Leilehua Golf Course Rd., Wahiawa, HI 96786) on August 9 and 10, 2021 from 6 to 9 p.m. During the EIS Scoping Virtual Open House, video presentations describing the Proposed Action can be viewed online at: *https://home.army.mil/hawaii/index.php/OAHUEIS* and oral comments will be taken via an accompanying call-in option. Written comments will be accepted during the EIS Scoping Virtual Open House and throughout the duration of the 40-day scoping process through an online comment platform or by mail or email. Additional in-person public comment stations may be made available, subject to procedural compliance with governmental guidance and restrictions related to COVID–19. Notification of the EIS Scoping Virtual Open House and in-person public comment stations will also be published and announced in local news media outlets and on the EIS website: *https://home.army.mil/hawaii/index.php/OAHUEIS.* Hard copy scoping materials are available by making a request to Amy Bugala, USAG–HI Public Affairs Officer at (808) 656–3160 or by email to: *usarmy.hawaii.comrel@mail.mil.*

James W. Satterwhite Jr.,

Army Federal Register Liaison Officer.

[FR Doc. 2021–15666 Filed 7–22–21; 8:45 am]

BILLING CODE 5061–AP–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–HA–0067]

Proposed Collection; Comment Request

AGENCY: The Office of the Assistant Secretary of Defense for Health Affairs, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Health Agency, ATTN: Maj Nathan Reynolds, 7700 Arlington Blvd., STE 5158, 3M546B, Falls Church, VA 22042 or call 703–681–5101.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD COVID–19 Vaccine Questionnaire; OMB Control Number 0720–0069.

Needs and Uses: The purpose of the DoD COVID–19 Vaccine Questionnaire is as follows: (1) Exercise due-diligence to reach out to the vast majority of our authorized vaccine eligible population (but has not received the COVID–19 vaccine per Military Health System records) with instructions on how to receive the vaccine. (2) Understand existing vaccine demand to adjust. (3) Inform future (*i.e.* booster) vaccination efforts. (4) Lift an administrative burden from the military treatment facilities by executing a standardized survey at the HQ level. (5) Remind message/questionnaire recipients to have their medical record updated with their vaccination as applicable.

Affected Public: Individuals or households.

Annual Burden Hours: 19,000.

Number of Respondents: 570,000.

Responses per Respondent: 1.

Annual Responses: 570,000.

Average Burden per Response: 2 minutes.

Frequency: One time.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2021–15758 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0069]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela Duncan at the Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100 or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Surrogate Association for DoD Self-Service (DS) Logon; DD Form 3005; OMB Control Number 0704–0559.

Needs and Uses: This information collection is needed to obtain the necessary data to establish eligibility for a DS Logon credential and enrollment in DEERS. This information shall be used to establish an individual's eligibility for DEERS enrollment and DS Logon credential issuance as a surrogate. Information is collected via the DD Form 3005, ''Application for Surrogate Association for DoD Self-Service (DS) Logon,'' and used to establish a record in DEERS and issue a DS Logon credential in accordance with DoDM 1341.02, Volume 1. The information that is collected may be released to Federal and State agencies and private entities, on matters relating to utilization review, professional quality assurance, program integrity, civil and criminal litigation, and access to Federal government facilities, computer systems, networks, and controlled areas.

Affected Public: Individuals or households.

Annual Burden Hours: 834 hours.

Number of Respondents: 5,000.

Responses per Respondent: 1.

Annual Responses: 5,000.

Average Burden per Response: 10 minutes.

Frequency: On occasion.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–15760 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0074]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela Duncan at the Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100 or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Medical Screening of Military Personnel-Medical History Report and Accession Medical History Report; DD Form 2807–1/DD Form 2807–2; OMB Control Number 0704–0413.

Needs and Uses: This information collected is the basis for determining medical eligibility of applicants for entry in the Armed Forces. This information is needed to determine the medical qualifications of applicants based upon their current and past medical history. The information obtained on the DD Form 2807–2 ensures the recruiter that an applicant have identified any medical disqualifying condition(s) prior to application process and meets the Congressional requirements to obtain both the applicants Health Care provider and Insurance provider. Additionally, it allows the military examining physician to obtain medical records critical to evaluating the applicant's medical condition(s) prior to their medical examination. The DD Form 2807–1 is needed as part of the required medical examination to assist physicians in making determinations as to acceptability of applicants for military service and verifies disqualifying medical condition(s) noted on the accession medical history report form.

Affected Public: Individuals or households.

Annual Burden Hours: 128,834 hours.

Number of Respondents: 773,003.

Responses per Respondent: 1.

Annual Responses: 773,003.

Average Burden per Response: 10 minutes.

Frequency: On occasion.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2021–15757 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0068]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela Duncan at the Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100 or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: SAPR/SHARP Survey; OMB Control Number 0704–0608.

Needs and Uses: NORC at the University of Chicago, in collaboration with the United States Naval Academy (USNA) Sexual Assault Prevention and Response (SAPR) staff and the United States Military Academy (USMA) sexual harassment/assault response and prevention (SHARP) staff, is conducting the SAPR/SHARP Surveys (a baseline survey and one follow-up survey) with USNA students (midshipmen) and USMA students (cadets) with funding support from the Sexual Assault Prevention and Response Office. The purpose of the overall study is to determine the effectiveness of the academy prevention programming in addressing sexual harassment and sexual assault. The survey assesses topics such as rape myth acceptance, descriptive behavioral norms at the respective academies, experiences of sexual harassment and sexual assault, alcohol-related sex expectancies, witnessing experiences that might call for bystander intervention to prevent sexual harassment and/or sexual assault, and personal responses when exposed to these situations. The surveys are voluntary. Data are aggregated by appropriate sociodemographic categories (sex, sexual orientation, race/ethnicity, and varsity athletic participation; sociodemographic responses will be recoded as binary indicators to prevent anyone from figuring out an individual participant's

identity based on unique characteristics). The results of this survey will be used by the Service Academies to evaluate and update their prevention programming.

Affected Public: Individuals or households.

Annual Burden Hours: 1,100.

Number of Respondents: 4,400.

Responses per Respondent: 1.

Annual Responses: 4,400.

Average Burden per Response: 15 minutes.

Frequency: On occasion (baseline in summer 2021; follow-up in spring 2023).

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–15770 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0072]

Proposed Collection; Comment Request

AGENCY: Defense Counterintelligence and Security Agency, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Counterintelligence and Security Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Counterintelligence and Security Agency, 27130 Telegraph Rd., Quantico, VA 22134–2253 ATTN: Ms. Stepheny Fanning, or call (571) 305–6685.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Transitional Compensation for Abused Dependents (TCAD); DD Form 2698; OMB Control Number 0704–0578.

Needs and Uses: The information collection requirement is necessary to establish eligibility, determine the number of payments, determine the number of dependents, determine the amount of compensation, and direct payment to the abused dependent(s).

Affected Public: Individuals or Households.

Annual Burden Hours: 166.7.

Number of Respondents: 500.

Responses per Respondent: 1.

Annual Responses: 500.

Average Burden per Response: 20 minutes.

Frequency: On occasion.

Respondents are abused dependents or former dependents, or legal representatives of abused dependents or former dependents, of service members who are convicted or administratively separated from military service due to a dependent abuse offense. In order to receive the benefit, the recipient must complete the required information in DD Form 2698.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–15762 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0071]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela Duncan at the Department of Defense, Washington

Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100 or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Record of Military Processing—Armed Forces of the United States; DD Form 1966/USMEPCOM FORM 680–3A–E; OMB Control Number 0704–0173.

Needs and Uses: Title 10 U.S. Code, Sections 504, 505, 508, and 1012, Title 14, U.S. Code, Sections 351 and 632; and Title 50 U.S. Code, Appendix Section 451, and E.O. 9397 require applicants to meet standards for enlistment into the Armed Forces. This information collection is the basis for determining eligibility of applicants for enlistment in the Armed Forces and is needed to verify data given by the applicant and to determine his/her qualification of enlistment. The information collected aids in the determination of qualifications, terms of service, and grade in which a person, if eligible, will enter active duty or reserve status. The information collected is used to feed other DoD and service–specific forms that later would be used to issue identification cards and receive benefits associated with military service.

Affected public: Individuals or households.

Annual Burden Hours: 296,100 hours.

Number of Respondents: 423,000.

Responses per Respondent: 2.

Annual Responses: 846,000.

Average Rurden per Response: 21 minutes.

Frequency: On occasion.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–15772 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0070]

Proposed Collection; Comment Request

AGENCY: Office of the Chief Information Officer, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Chief Information Officer announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela Duncan at the Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100 or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Basic Employee and Security Tracking Systems (BEAST); OMB Control Number 0704–0507.

Needs and Uses: The information collection requirement is necessary to obtain, track, and record the personnel security data, training information, and travel history within the White House Military Office (WHMO) and White House Communications Agency (WHCA).

Affected Public: Individuals or Households.

Annual Burden Hours: 38.

Number of Respondents: 150.

Responses per Respondent: 1.

Annual Responses: 150.

Average Burden per Response: 0.25 hours (15 minutes).

Frequency: On Occasion.

Respondents are DoD contractors, retired military members who have departed the agency, and agency visitors. The data collected is used for security background checks, training records, and also to encompass the historical travel records of members of the agency. This data collection is essential in maintaining the integrity of the agency's personnel, training, and travel programs.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–15761 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0073]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by September 21, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela Duncan at the Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100 or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD Child Development Program (CDP)—Criminal History; DD Form 2981; OMB Control Number 0704–0516.

Needs and Uses: The information collection requirement is necessary to obtain a self-reported record of criminal history from each employee, contractor, volunteer, family child care provider, and family child care adult family member residing in the home. Authority is granted by 42 United States Code 13041 which requires the application for individuals who are seeking work for an agency of the Federal Government, or for a facility or program operated by (or through contract with) the Federal Government, contain a question asking whether the individual has ever been arrested for or charged with a crime involving a child, and if so requiring a description of the disposition of the arrest or charge. Individuals who are interested in working for the DoD or for a program operated by or through a contract with the DoD must complete the form prior to working with children under the age of 18 years.

Affected Public: Individuals or households.

Annual Burden Hours: 2,000 hours.

Number of Respondents: 8,000.

Responses per Respondent: 1.

Annual Responses: 8,000.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: July 20, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2021–15763 Filed 7–22–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board

Meeting

AGENCY: National Assessment Governing Board, Department of Education.

ACTION: Notice of open and closed virtual meetings.

SUMMARY: This notice sets forth the agenda for the National Assessment Governing Board (hereafter referred to as Governing Board) meeting scheduled for August 5–6, 2021. This notice provides information about the meeting to members of the public who may be interested in attending and/or providing written comments related to the work of the Governing Board. Notice of this meeting is required under the Federal Advisory Committee Act (FACA).

ADDRESSES: In-person attendance for this meeting is for members and staff due to COVID–19 social distancing requirements. Governing Board members and staff will meet at the Tysons Corner Ritz-Carlton, 1700 Tysons Boulevard, McLean, VA 22102. Virtual attendance for all Governing Board open sessions will be accessible to members of the public who register per the instructions provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu, Executive Officer/Designated Federal Official for the Governing Board, 800 North Capitol Street NW, Suite 825, Washington, DC 20002, telephone: (202) 357–6906, fax: (202) 357–6945, email: *Munira.Mwalimu@ed.gov.*

SUPPLEMENTARY INFORMATION: *Statutory Authority and Function:* The Governing Board is established under the National Assessment of Educational Progress Authorization Act, Title III of Public Law 107–279. Information on the Governing Board and its work can be found at *www.nagb.gov.*

The Governing Board is established to formulate policy for the National Assessment of Educational Progress (NAEP) administered by the National Center for Education Statistics (NCES). The Governing Board's responsibilities include the following: (1) Selecting subject areas to be assessed; (2) developing assessment frameworks and specifications; (3) developing appropriate student achievement levels for each grade and subject tested; (4) developing standards and procedures for interstate and national comparisons; (5) improving the form and use of NAEP; (6) developing guidelines for reporting and disseminating results; and (7) releasing initial NAEP results to the public.

Standing Committee Meetings

The Governing Board's standing committees will meet to conduct regularly scheduled work planned for this Quarterly Board Meeting and any items undertaken by committees for consideration by the full Governing Board. (Please see committee meeting minutes for previous meetings, available at *https://www.nagb.gov/governing-board/quarterly-board-meetings.html.*) Committee meeting agendas will be posted on the Governing Board's website *www.nagb.gov* five business days prior to the meetings. Online registration for virtual access to the pen sessions of the Governing Board and committee meetings will also be posted at *www.nagb.gov* five working days prior to each meeting.

Thursday, July 22, 2021
Reporting and Dissemination Committee
3:00 p.m.–5:00 p.m. (Open Session)

Wednesday, July 28, 2021
Nominations Committee
5:30 p.m.–6:30 p.m. (Closed Session)

Tuesday, August 3, 2021
Committee on Standards, Design & Methodology
1:00 p.m.–1:40 p.m. (Closed Session)
1:40 p.m.–3:00 p.m. (Open Session)

Thursday, August 5, 2021
Assessment Development Committee
9:00 a.m. to 10:00 a.m. (Open Session)

Thursday, August 5, 2021
Executive Committee Meeting
10:00 a.m.–11:30 a.m. (Open Session)
11:30 a.m.–12:00 p.m. (Closed Session)

Quarterly Governing Board Meeting

The plenary sessions of the August 5–6, 2021 quarterly meeting of the Governing Board will be held on the following dates and times:

Thursday, August 5, 2021: Open Meeting: 1:15 p.m.–5:30 p.m.

Friday, August 6, 2021: Closed Meeting: 10:00 a.m.–1:15 p.m.; Open Meeting: 2:15 p.m.–4:00 p.m.

August 5, 2021: Open Meetings

On Thursday, August 5, 2021, the Governing Board will meet in open session from 1:15 p.m. to 5:30 p.m. From 1:15 p.m. to 1:30 p.m., Chair Haley Barbour will welcome members, review and approve the August 5–6, 2021 quarterly Governing Board meeting agenda, and approve minutes from the May 14–15, 2021 quarterly Governing Board meeting.

From 1:30 p.m. to 1:45 p.m., Lesley Muldoon, Executive Director of the Governing Board, will provide an update on ongoing work, followed by an update from the National Center for Education Statistics (NCES) from 1:45 p.m. to 2:15 p.m.

From 2:15 p.m. to 2:45 p.m., the Chairs of Standing Committees will provide updates on ongoing work. Two action items will be presented for Governing Board vote based on recommendations made by the Executive Committee—the nomination for Governing Board Vice Chair for the term October 1, 2021–September 30, 2022, and a recommendation to change the Long-Term Trend Administration in 2022 from 17-year-olds to 9-year-olds.

After a 15-minute break, from 3:00 p.m. to 4:00 p.m., the Governing Board will meet in open session to discuss and take action on the NAEP Reading Framework. From 4:00 p.m. to 5:30 p.m., the Governing Board will receive an overview of the Technology and Engineering Literacy Assessment.

The Thursday, August 5, 2021 session of the Governing Board meeting will adjourn at 5:30 p.m.

August 6, 2021

On Friday, August 6, 2021, the Governing Board meeting will convene in two closed sessions from 12:30 p.m. to 1:15 p.m. and thereafter in open session from 2:15 p.m. to 4:00 p.m.

The first closed session will convene from 10:00 a.m. to 11:30 a.m. to receive a briefing from Peggy Carr, Associate Commissioner of NCES, and Lesley Muldoon on the NAEP Budget and Assessment Schedule. The briefing and Governing Board discussions may affect current and future NAEP contracts and budgets and must be kept confidential to maintain the integrity of the federal acquisition process. Public disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 of the United States Code.

The second closed session will convene from 11:45 a.m. to 1:15 p.m. to receive briefings from NCES on two upcoming releases—the Long-Term Trend Assessment and the High School Transcript Study. This session must be closed because both sets of results are not yet publicly released. Such matters are protected by exemption 9(B) of § 552b of Title 5 U.S.C.

The Governing Board will reconvene in open session from 2:15 p.m. to 3:30 p.m. to receive a briefing from Ebony Walton, NCES, on understanding patterns of similar NAEP results across different subject areas. Following this session, from 3:30 p.m. to 4:00 p.m., departing members whose terms of service will end on September 30, 2021 will provide farewell remarks. The August 6, 2021 session of the Governing Board meeting will adjourn at 4:30 p.m.

The Quarterly Board meeting and committee meeting agendas, together with meeting materials will be posted on the Governing Board's website at *www.nagb.gov* no later than five working days prior to each meeting.

Virtual attendance for all open sessions will be accessible to members of the public via online registration only at *www.nagb.gov* 5 business days prior to each meeting.

Access to Records of the Meeting: Pursuant to FACA requirements, the public may also inspect the meeting materials at *www.nagb.gov* five business days prior to each meeting. The official verbatim transcripts of the public meeting sessions will be available for public inspection no later than 30 calendar days following each meeting.

Reasonable Accommodations: The meeting is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice no later than ten working days prior to each meeting. Written comments related to the work of the Governing Board may be submitted electronically or in hard copy to the attention of the Executive Officer/Designated Federal Official (see contact information noted above).

Public Participation: Members of the public may virtually attend and attend in person all open sessions of the standing committee and full Governing Board meetings via advance registration. A link to the registration page will be posted on *www.nagb.gov* five business days prior to each meeting date.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the Adobe website. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Public Law 107–279, Title III—National Assessment of Educational Progress § 301.

Lesley Muldoon,

Executive Director, National Assessment Governing Board (NAGB), U.S. Department of Education.

[FR Doc. 2021–15764 Filed 7–22–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0109]

Agency Information Collection Activities; Comment Request; Consolidated Annual Report (CAR) for the Carl D. Perkins Career and Technical Education Act of 2006

AGENCY: Office of Career, Technical, and Adult Education (OCTAE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before September 21, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0109. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting

comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Braden Goetz, 202–245–7405.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Consolidated Annual Report (CAR) for the Carl D. Perkins Career and Technical Education Act of 2006.

OMB Control Number: 1830–0569.

Type of Review: A revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 53.

Total Estimated Number of Annual Burden Hours: 12,632.

Abstract: This information collection is used by the U.S. Department of Education to gather annual performance and financial data from eligible agencies under the Carl D. Perkins Career and Technical Education Act of 2006 as amended by the Strengthening Career and Technical Education for the 21st Century Act (Pub. L. 115–224). We are proposing to revise the ICR to remove the option to report enrollment and performance data via the EDFacts system, amend the Fiscal Responsibility section of the Narrative Performance Report to collect additional data about subgrants and their recipients, and to make clarifying changes to some of the instructions.

Dated: July 20, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–15688 Filed 7–22–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Number: PR21–20–001.

Applicants: Red Bluff Express Pipeline, LLC.

Description: Tariff filing per 284.123(b),(e)/: Red Bluff Express Pipeline, LLC Amended SOC Effective January 1, 2021 to be effective 1/1/2021.

Filed Date: 7/16/2021.

Accession Number: 202107165060.

Comments/Protests Due: 5 p.m. ET 7/30/2021.

Docket Number: PR21–55–000.

Applicants: Louisville Gas and Electric Company.

Description: Tariff filing per 284.123(b),(e)/: Operating Statement Rate Change Exhibit A to be effective 6/28/2021.

Filed Date: 7/16/2021.

Accession Number: 202107165026.

Comments/Protests Due: 5 p.m. ET 8/6/2021.

Docket Numbers: RP21–949–001.

Applicants: LA Storage, LLC.

Description: Tariff Amendment: Amendment to Correct Negotiated Non-Conforming Agreement to be effective 7/1/2021.

Filed Date: 7/16/21.

Accession Number: 20210716–5157.

Comments Due: 5 p.m. ET 7/28/21.

Docket Numbers: RP21–969–000.

Applicants: Arlington Storage Company, LLC.

Description: Compliance filing Informational Filing Concerning MBR Authority.

Filed Date: 7/16/21.

Accession Number: 20210716–5138.

Comments Due: 5 p.m. ET 7/28/21.

Docket Numbers: RP21–970–000.

Applicants: Stagecoach Pipeline & Storage Company LLC.

Description: Compliance filing Informational Filing Concerning MBR Authority.

Filed Date: 7/16/21.

Accession Number: 20210716–5141.

Comments Due: 5 p.m. ET 7/28/21.

Docket Numbers: RP21–971–000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: Compliance filing Informational Filing Concerning Market-Based Rate Authority.

Filed Date: 7/16/21.

Accession Number: 20210716–5142.

Comments Due: 5 p.m. ET 7/28/21.

Docket Numbers: RP21–972–000.

Applicants: Colorado Interstate Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Wobbe Number Modification Filing to be effective 8/15/2021.

Filed Date: 7/16/21.

Accession Number: 20210716–5150.

Comments Due: 5 p.m. ET 7/28/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 19, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–15696 Filed 7–22–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–90–000]

Basin Electric Power Cooperative and North Iowa Municipal Electric Cooperative Association v. Southwest Power Pool, Inc.; Notice of Complaint

Take notice that on July 16, 2021, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e and 825e, and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Basin Electric Power Cooperative and North Iowa Municipal Electric Cooperative Association (Complainants) filed a formal complaint against Southwest Power Pool, Inc. (Respondent), alleging that Southwest Power Pool, Inc. violated the terms of the Southwest Power Pool, Inc. Open Access Transmission Tariff by de-committing several Basin Electric Power Cooperative and North Iowa Municipal Electric Cooperative Association Resources that were committed through the Multi-Day Reliability Assessment process for reasons other than addressing an Emergency Condition, all as more fully explained in its complaint.

The Complainants certify that copies of the complaint were served on the contacts listed for Respondent in the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov,* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 9, 2021.

Dated: July 19, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–15700 Filed 7–22–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–84–000]

Altavista Solar, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On July 16, 2021, the Commission issued an order in Docket No. EL21–84–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation into whether Altavista Solar, LLC's proposed Rate Schedule [1] is unjust, unreasonable, unduly discriminatory, or preferential, or otherwise unlawful. *Altavista Solar, LLC,* 176 FERC ¶ 61,020 (2021).

The refund effective date in Docket No. EL21–84–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL21–84–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2020), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Dated: July 19, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–15697 Filed 7–22–21; 8:45 am]

BILLING CODE 6717–01–P

[1] Altavista Solar, LLC, Tariffs, Rates Schedules, and Agreements, Reactive Supply Service, Rate Schedule FERC No. 1, 0.0.0.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21–106–000.

Applicants: Green Mountain Power Corporation, Vermont Transco LLC, Vermont Electric Power Company.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Green Mountain Power Corporation.

Filed Date: 7/16/21.

Accession Number: 20210716–5173.

Comments Due: 5 p.m. ET 8/6/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1508–007.
Applicants: Entergy Arkansas, Inc.
Description: Report Filing: EAL Refund Report (ER13–1508) to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5121.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER19–229–006.
Applicants: Allegheny Ridge Wind Farm, LLC.
Description: Report Filing: Refund Report Under Docket ER19–229 to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5059.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–43–002.
Applicants: Exelon Generation Company, LLC.
Description: Compliance filing: Supplemental Report Regarding a Spot Market Sale of Electricity in WECC to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5112.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–51–002.
Applicants: BP Energy Company.
Description: Compliance filing: Supplemental Report Regarding Certain WECC Spot Market Sales to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5134.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–57–001.
Applicants: Shell Energy North America (US), L.P.
Description: Compliance filing: Supplement to Oct 7, 2020 Filing Regarding Spot Market Sales Above Soft Cap to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5136.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–61–002.
Applicants: El Paso Electric Company.
Description: Compliance filing: WECC Soft Cap Justification to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5132.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–410–003.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: Compliance filing: Revisions to Generator Interconnection Procedures to be effective 1/13/2021.
Filed Date: 7/19/21.
Accession Number: 20210719–5147.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2009–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Errata to correct metadata in ER21–2009, SA No. 5817; Queue No. AF2–085 to be effective 9/15/2020.
Filed Date: 7/19/21.
Accession Number: 20210719–5078.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2446–000.
Applicants: Rainbow Energy Center, LLC.
Description: Initial rate filing: Rainbow Energy Center, LLC Reactive Power Filing to be effective 9/1/2021.
Filed Date: 7/16/21.
Accession Number: 20210716–5164.
Comments Due: 5 p.m. ET 8/6/21.

Docket Numbers: ER21–2447–000.
Applicants: Versant Power.
Description: Versant Power submits Petition for Limited Waiver of Unreserved Transmission Use Penalty Policy.
Filed Date: 7/16/21.
Accession Number: 20210716–5174.
Comments Due: 5 p.m. ET 8/6/21.

Docket Numbers: ER21–2448–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA, Service Agreement No. 6106; Queue No. AD2–213 to be effective 6/17/2021.
Filed Date: 7/19/21.
Accession Number: 20210719–5028.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2449–000.
Applicants: Assembly Solar II, LLC.
Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 10/1/2021.
Filed Date: 7/19/21.
Accession Number: 20210719–5056.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2451–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original ISA No. 6101; Queue No. AE1–060 to be effective 6/17/2021.
Filed Date: 7/19/21.
Accession Number: 20210719–5088.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2452–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: Second Amended GIA & DSA Johanna Energy Center, LLC and Terminate GIA eTariff to be effective 9/18/2021.
Filed Date: 7/19/21.
Accession Number: 20210719–5092.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2453–000.
Applicants: Exelon Generation Company, LLC.
Description: Compliance filing: Report Regarding a Spot Market Sale of Electricity in WECC to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5097.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2454–000.
Applicants: Rainbow Energy Marketing Corporation.
Description: Compliance filing: 2020 Soft Price Cap Compliance Filing to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5098.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2455–000.
Applicants: California Independent System Operator Corporation.
Description: § 205(d) Rate Filing: 2021–07–19 FERC Order No. 2222 Compliance Filing to be effective 12/31/9998.
Filed Date: 7/19/21.
Accession Number: 20210719–5100.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2456–000.
Applicants: Rainbow Energy Marketing Corporation.
Description: Compliance filing: 2021 Soft Price Cap Compliance Filing to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5101.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2457–000.
Applicants: Tri-State Generation and Transmission Association, Inc.
Description: Compliance filing: 2021 Soft Price Cap Compliance Filing to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5106.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2458–000.
Applicants: Cedar Creek Wind Energy, LLC.
Description: § 205(d) Rate Filing: Amended Tariff Records for Certificates of Concurrence to be effective 7/6/2021.
Filed Date: 7/19/21.
Accession Number: 20210719–5117.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2459–000.
Applicants: Tenaska Power Services Co.
Description: Compliance filing: Filing re Certain Spot Sales at Prices Exceeding West-Wide Soft Cap-June 2021 to be effective N/A.
Filed Date: 7/19/21.
Accession Number: 20210719–5122.
Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2460–000.
Applicants: New York Independent System Operator, Inc.
Description: Compliance filing: NYISO NOPR compliance filing of tariff

revisions related to Order No. 2222 to be effective 12/31/9998.

Filed Date: 7/19/21.

Accession Number: 20210719–5126.

Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2461–000.

Applicants: TransAlta Energy Marketing (U.S.) Inc.

Description: Compliance filing: Notice and Justification for Spot Sales above WECC Soft Cap to be effective N/A.

Filed Date: 7/19/21.

Accession Number: 20210719–5142.

Comments Due: 5 p.m. ET 8/9/21.

Docket Numbers: ER21–2462–000.

Applicants: Sempra Gas & Power Marketing, LLC.

Description: Compliance filing: WECC Cost Justification Filing to be effective N/A.

Filed Date: 7/19/21.

Accession Number: 20210719–5158.

Comments Due: 5 p.m. ET 8/9/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 19, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–15695 Filed 7–22–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9057–5]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed July 12, 2021 10 a.m. EST Through July 19, 2021 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20210099, Draft Supplement, CHSRA, CA, California High-Speed Rail San Francisco to San Jose Project Section Revised Draft Environmental Impact Report/Supplemental Draft Environmental Impact Statement, Comment Period Ends: 09/08/2021, Contact: Scott Rothenberg 916–403–6936.

EIS No. 20210100, Draft, FERC, LA, Evangeline Pass Expansion Project, Comment Period Ends: 09/07/2021, Contact: Office of External Affairs 866–208–3372.

Amended Notice

EIS No. 20210051, Draft, USN, CA, Navy Old Town Campus Revitalization, Comment Period Ends: 08/12/2021, Contact: Ron Bochenek 619–705–5560.

Revision to FR Notice Published 05/14/2021; Extending the Comment Period from 07/13/2021 to 08/12/2021.

EIS No. 20210078, Draft, UDOT, UT, Little Cottonwood Canyon Environmental Impact Statement Wasatch Boulevard to Alta, Comment Period Ends: 09/03/2021, Contact: Josh Van Jura 801–231–8452.

Revision to FR Notice Published 06/25/2021; Extending the Comment Period from 08/09/2021 to 09/03/2021.

Dated: July 19, 2021.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2021–15678 Filed 7–22–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0027; FRL–8764–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Bulk Gasoline Terminals (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Bulk Gasoline Terminals (EPA ICR Number 0664.13, OMB Control Number 2060–0006), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2021. Public comments were previously requested, via the **Federal Register**, on May 12, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently-valid OMB control number.

DATES: Additional comments may be submitted on or before August 23, 2021.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0027 online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov,* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW,

Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of gasoline bulk terminals are required to comply with reporting and record keeping requirements for the General Provisions (40 CFR part 60, subpart A), as well as for the applicable standards in 40 CFR part 60, subpart XXX. This includes submitting initial notifications, performance tests, and maintaining records of inspections and the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Bulk gasoline terminals.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart XX).

Estimated number of respondents: 214 (total).

Frequency of response: Initially.

Total estimated burden: 70,900 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $8,320,000 (per year), which includes $0 for annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is an adjustment increase in the total estimated burden as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the burden and cost estimates occurred because of an increase in the number of existing respondents. The number of existing respondents in this ICR has been adjusted based on data collected from EPA's Enforcement and Compliance History Online (ECHO) database. A review of the ECHO data based on NAICS code 424710 (Petroleum Bulk Stations and Terminals), availability of EIS ID, identification as subject to Subpart XX, and reported to the National Emissions Inventory identified approximately 214 active sources. This ICR reflects a more accurate estimate of the number of existing respondents. The number of new respondents per year has not been adjusted due to uncertainty in current industry trends. The overall result is an increase in burden hours and costs.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–15661 Filed 7–22–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2017–0752; FRL–8766–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Background Checks for Contractor Employees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Background Checks for Contractor Employees (EPA ICR Number 2159.08, OMB Control Number 2030–0043) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2021. Public comments were previously requested via the **Federal Register** on January 21, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before August 23, 2021.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OARM–2017–0752, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Denise Clarke, Policy Training and Oversight Division, Office of Acquisition Solutions (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–8414; email address: *clarke.denise@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The EPA uses contractors to perform services throughout the nation with regard to environmental emergencies involving the release, or threatened release, of oil, radioactive materials, or hazardous chemicals that may potentially affect communities and the surrounding environment. The Agency may request contractors responding to any of these types of incidents to conduct background checks and apply Government-established suitability criteria in Title 5 CFR Administrative Personnel 731.104 *Appointments Subject to Investigation,* 732.201 *Sensitivity Level Designations and Investigative Requirements,* and 736.102 *Notice to Investigative Sources* when determining whether employees are acceptable to perform on given sites or on specific projects. In addition to emergency response contractors, EPA may require background checks for contractor personnel working in sensitive sites or sensitive projects. The background checks and application of the Government's suitability criteria must be completed prior to contract employee performance. The contractor shall maintain records associated with all background checks. Background checks cover citizenship or valid visa status, criminal convictions, weapons offenses, felony convictions, and parties prohibited from receiving federal contracts.

Form numbers: None.

Respondents/affected entities: Private Contractors.

Respondent's obligation to respond: Required to obtain a benefit.

Estimated number of respondents: 1,000 (total).

Frequency of response: Annual.

Total estimated burden: 1,000 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $208,720 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in estimates: There is no change in the hours in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–15639 Filed 7–22–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OARM–2018–0065; FRL–8765–01–OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Drug Testing for Contractor Employees (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Drug Testing for Contractor Employees (EPA ICR No. 2183.08, OMB Control No. 2030–0044) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through September 30, 2021. Public comments were previously requested via the **Federal Register** on March 8, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before August 23, 2021.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OARM–2018–0065, online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Thomas Valentino, Policy Training and Oversight Division, Office of Acquisition Solutions (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–4522; email address: *valentino.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR applies to contractors who perform response services at sensitive sites with serious security concerns where the Agency and public interest would best be protected through drug testing. It requires the contractor to test its employees for the use of marijuana, cocaine, opiates, amphetamines, phencyclidine (PCP), and any other controlled substances. Only contractor employees who have been tested within the previous 90 calendar days and have passing drug test results may be directly engaged in on-site response work and/or on-site related activities at designated sites with significant security concerns. The Agency may request contractors responding to any of these types of incidents to conduct drug testing and apply Government-established suitability criteria in title 5 CFR 731.104, *Appointments subject to investigation,* 732.201, *Sensitivity level designations and investigative requirements,* and 736.102, *Notice to investigative sources,* when determining whether employees are acceptable to perform on given sites or on specific projects.

Form numbers: None.

Respondents/affected entities: Private contractors.

Respondent's obligation to respond: Required to obtain a benefit per title 5 CFR 731.104.

Estimated number of respondents: 500 (total).

Frequency of response: Annual.

Total estimated burden: 1,125 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $133,010 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in estimates: There is no change in the hours in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2021–15640 Filed 7–22–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX; FR ID 38901]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments and recommendations for the proposed

information collection should be submitted on or before August 23, 2021.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–XXXX.

Title: Advanced Methods to Target and Eliminate Unlawful Robocalls, Fourth Report and Order, CG Docket No. 17–59, FCC 20–187.

Type of Review: New information collection.

Form Number: N/A.

Total Annual Burden: 199,412 hours.

Respondents: Business or other for-profit entities.

Number of Respondents: 6,493 respondents; 582,434 responses.

Estimated Time per Response: .25 to 40 hours.

Frequency of Response: On-occasion reporting requirement, on-going reporting requirement and Third-party Disclosure requirement.

Total Annual Cost: No cost.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for these collections are contained in sections 4(i), 201, 202, 217, 227, 227b, 251(e), 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 201, 202, 217, 227, 227b, 251(e), 303(r), 403.

Needs and Uses: This notice and request for comments seeks to establish a new information collection as it pertains to the Advanced Methods to Target and Eliminate Unlawful Robocalls Fourth Report and Order (''Call Blocking Fourth Report and Order''), FCC 20–187. Unwanted and illegal robocalls have long been the Federal Communication Commission's (''Commission'') top source of consumer complaints and one of the Commission's top consumer protection priorities. In 2019, Congress passed the Pallone-Thune Telephone Robocall Abuse Criminal Enforcement and Deterrence (TRACED) Act. In addition to directing the Commission to mandate adoption of caller ID authentication technology and encourage voice service providers to block calls by establishing safe harbors, the TRACED Act directs the Commission to ensure that both consumers and callers are provided with transparency and effective redress when calls are blocked in error. In the Call Blocking Fourth Report and Order, the Commission took several steps to better protect consumers from unwanted and illegal robocalls, and implement the TRACED Act. The Commission expanded the existing safe harbor for blocking of calls, established affirmative requirements to ensure that voice service providers better police their networks against illegal calls, and adopted several transparency and redress requirements to ensure that erroneous blocking can be quickly identified and remedied.

Call Blocking Fourth Report and Order, FCC 20–187, Paras. 22–31, 47 CFR 64.1200(n)(2)

A voice service provider must: . . . Take steps to effectively mitigate illegal traffic when it receives actual written notice of such traffic from the Commission through its Enforcement Bureau. In providing notice, the Enforcement Bureau shall identify with as much particularity as possible the suspected traffic; provide the basis for the Enforcement Bureau's reasonable belief that the identified traffic is unlawful; cite the statutory or regulatory provisions the suspected traffic appears to violate; and direct the voice service provider receiving the notice that it must comply with this section. Each notified provider must promptly investigate the identified traffic. Each notified provider must then promptly report the results of its investigation to the Enforcement Bureau, including any steps the provider has taken to effectively mitigate the identified traffic or an explanation as to why the provider has reasonably concluded that the identified calls were not illegal and what steps it took to reach that conclusion. Should the notified provider find that the traffic comes from an upstream provider with direct access to the U.S. Public Switched Telephone Network, that provider must promptly inform the Enforcement Bureau of the source of the traffic and, if possible, take steps to mitigate this traffic.

The first portion of the new information collection for which OMB approval is sought comes from the affirmative obligation adopted in the Call Blocking Fourth Report and Order that voice service providers effectively mitigate illegal traffic when notified of such traffic by the Commission's Enforcement Bureau. In adopting this requirement as well as the other affirmative obligations, the Commission made clear that, while most blocking is done by terminating voice service providers, originating and intermediate voice service providers are integral to stopping illegal calls. This requirement in particular gives the Commission an important tool in the fight to stop illegal calls.

Call Blocking Fourth Report and Order, FCC 20–187, Paras. 62–70, 47 CFR 64.1200(k)(10)

Any terminating provider that blocks calls on an opt-out or opt-in basis, either

itself or through a third-party blocking service, must provide, at the request of the subscriber to a number, at no additional charge and within 3 business days of such a request, a list of calls to that number, including the date and time of the call and the calling number, that the terminating provider or its designee blocked within the 28 days prior to the request.

The second portion of the new information collection for which OMB approval is sought comes from the requirement in the Call Blocking Fourth Report and Order that any terminating voice service provider that blocks calls on an opt-in or opt-out basis must provide, on the request of the subscriber to a particular number, a list of all calls intended for that number that the voice service provider or its designee has blocked. The list must include the prior 28 days of blocked calls and must be provided to the subscriber within 3 business days. The TRACED Act expressly directs the Commission to ensure that both consumers and callers are provided with transparency. In the Call Blocking Fourth Report and Order, the Commission determined that, while opt-in or opt-out blocking must already be disclosed to consumers, a consumer may be unaware that particular calls are blocked absent such a list. Consumers can use the list to determine whether to opt out of blocking services or reach out to callers whose calls may have been blocked.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–15709 Filed 7–22–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings; Notice of Change in Subject Matter of Agency Sunshine Act Meeting

Pursuant to the provisions of subsection (e)(2) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 10:01 a.m. on Tuesday, July 20, 2021, the Corporation's Board of Directors determined, on motion of Director Martin J. Gruenberg (Appointive), seconded by Director David Uejio (Acting Director, Consumer Financial Protection Bureau), and concurred in by Director Michael J. Hsu (Acting Comptroller of the Currency), and by Chairman Jelena McWilliams, that Corporation business required the deferral of an item on the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Memorandum and resolution re: Notice of Proposed Rulemaking on Revisions to Standardized Approach for Calculating the Exposure Amount of Derivative Contracts.

The Board further determined, by the same majority vote, that no notice earlier than July 20, 2021, of the change in the subject matter of the meeting was practicable.

Dated this the 20th day of July, 2021.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2021–15807 Filed 7–21–21; 4:15 pm]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 9, 2021.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Senior Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard*; to acquire additional voting shares of First BanCorp, and thereby indirectly acquire voting shares of FirstBank Puerto Rico, both of San Juan, Puerto Rico.

2. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard*; to acquire additional voting shares of OFG Bancorp, and thereby indirectly acquire voting shares of Oriental Bank, both of San Juan, Puerto Rico.

B. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard*; to acquire voting shares of BankUnited, Inc., and thereby indirectly acquire voting shares of BankUnited, NA, both of Miami Lakes, Florida.

Board of Governors of the Federal Reserve System, July 20, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–15712 Filed 7–22–21; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0027; Docket No. 2021–0001; Sequence No. 5]

Information Collection; General Services Administration Acquisition Regulation; Contract Administration, Quality Assurance (GSA Forms 1678 and 308)

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the General

Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding contract administration and quality assurance.

DATES: Submit comments on or before: September 21, 2021.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB Control number 3090–0027. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0027, Contract Administration and Quality Assurance (GSA Forms 1678 and 308)''. Follow the instructions on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0027, Contract Administration and Quality Assurance (GSA Forms 1678 and 308)'', on your attached document.

If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090–0027, Contract Administration and Quality Assurance (GSA Forms 1678 and 308), in all correspondence related to this collection. Comments received generally will be posted without change to *regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three business days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Vernita Misidor, Procurement Analyst, General Services Acquisition Policy Division, at 202–357–9681 or via email to *vernita.misidor@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Under certain contracts, because of reliance on contractor inspection in lieu of Government inspection, GSA's Federal Acquisition Service requires documentation from its contractors to effectively monitor contractor performance and ensure that it will be able to take timely action should that performance be deficient.

B. Annual Reporting Burden

GSA Form 1678

Annual Responses: 250,0000.
Responses per Respondent: 1.
Total Annual Responses: 250,0000.
Hours per Response: 0.008.
Total Burden Hours: 2,000.

GSA Form 308

Annual Responses: 2,600.
Responses per Respondent: 1.
Total Annual Responses: 2,600.
Hours per Response: 0.08.
Total Burden Hours: 208.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0027, Contract Administration, Quality Assurance (GSA Forms 1678 and 308), in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2021–15745 Filed 7–22–21; 8:45 am]

BILLING CODE 6820–61–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0248; Docket No. 2021–0001; Sequence No. 6]

Information Collection; General Services Administration Acquisition Regulation; Solicitation Provisions and Contract Clauses; Placement of Orders Clause; and Ordering Information Clause

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding solicitation provisions and contract clauses, placement of orders clause, and ordering information clause.

DATES: Submit comments on or before: September 21, 2021.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to *http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for Information Collection 3090–0248. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0248, Solicitation Provisions and Contract Clauses, Placement of Orders Clause, and Ordering Information Clause''.

Follow the instructions on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0248, Solicitation Provisions and Contract Clauses, Placement of Orders Clause, and Ordering Information Clause'' on your attached document.

If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Vernita Misidor, Procurement Analyst, GSA Acquisition Policy Division, by phone at 202–357–9681 or by email at *vernita.misidor@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA has various mission responsibilities related to the acquisition and provision of the Federal Acquisition Service's (FAS's) Stock, Special Order, and Federal Supply Schedule (FSS) Programs. These mission responsibilities generate requirements that are realized through the solicitation and award of various types of FAS contracts. Individual solicitations and resulting contracts may impose unique information collection and reporting requirements on contractors, not required by regulation, but necessary to evaluate particular program accomplishments and measure success in meeting program objectives.

As such, the General Services Administration Acquisition Regulation (GSAR) 516.506, Solicitation provision and clauses, specifically directs contracting officers to insert 552.216–72, Placement of Orders, and 552.216–73, Ordering Information, when the contract authorizes FAS and other activities to issue delivery or task orders. These clauses include information reporting requirements for Offerors to receive electronic orders through computer-to-computer Electronic Data Interchange (EDI).

B. Annual Reporting Burden

Respondents: 18,590.
Responses per Respondent: 1.
Annual Responses: 18,590.
Hours Per Response: .25.
Total Burden Hours: 4,648.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0248, Solicitation Provisions and Contract Clauses, Placement of Orders Clause, and Ordering Information Clause, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2021–15746 Filed 7–22–21; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Award of a Single-Source Unsolicited Grant To Fund the Community Education Group

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the award of approximately $5,000,000 annually in COVID–19 funding for a three-year period in response to an unsolicited application that has been submitted by the Community Education Group to support vaccine coverage, in particular for COVID–19.

DATES: The period for this award will be July 31, 2021 through July 30, 2024.

FOR FURTHER INFORMATION CONTACT: Stephanie Griswold, MPH, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H24–8, Atlanta, GA 30329, Telephone: 800–232–6348, E-Mail: *eocevent515@cdc.gov.*

SUPPLEMENTARY INFORMATION: The proposed work being funded aims to build the evidence base of effective interventions to improve vaccination coverage and to identify and implement strategies to reduce disparities in vaccination coverage in rural populations, specifically in West Virginia. Community Education Group (CEG) works to eliminate disparities in health outcomes and improve public health in disadvantaged populations and under-served communities by conducting research, training community health workers, educating and testing people who are hard to reach or at risk, sharing its expertise through national networks and local capacity building efforts, and advocating for practical and effective health policies that lead to social change.

This award is being made non-competitively because there is no current, pending, or planned funding opportunity announcement under which this proposal could compete.

The National Center for Immunization and Respiratory Diseases performed an objective review of the unsolicited proposal and determined that the proposal has merit and CEG is in a unique position to perform the activities contained within their proposal. CEG works to eliminate disparities in health outcomes and improve public health in disadvantaged populations and under-served communities by conducting research, training community health workers, educating and testing people who are hard to reach or at risk.

Summary of the Award

Recipient: Community Education Group (CEG).

Purpose of the Award: The purpose of the award is to build the evidence base of effective interventions to improve vaccination coverage and to identify and implement strategies to reduce disparities in vaccination coverage in rural populations. The proposal submitted was not solicited either formally or informally by any federal government official.

Amount of Award: $5,000,000 in Federal Fiscal Year (FYY) 2021 funds, and an estimated $5,000,000 for each subsequent year budget period, subject to availability of funds.

Period of Performance: July 31, 2021 through July 30, 2024.

Dated: July 20, 2021.

Joseph I. Hungate, III,

Deputy Director, Office of Financial Resources, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–15738 Filed 7–22–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10572 and CMS–10781]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 21, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ___, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10572 Transparency in Coverage Reporting by Qualified Health Plan Issuers

CMS–10781 FOIA/Privacy Act Requests for Medicare Claims Data via CMS FOIA Public Portal

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Transparency in Coverage Reporting by Qualified Health Plan Issuers; *Use:* Sections 1311(e)(3)(A)–(C) of the ACA, as implemented at 45 CFR 155.1040(a)–(c) and 156.220, establish standards for qualified health plan (QHP) issuers to submit specific information related to transparency in coverage. QHP issuers are required to post and make data related to transparency in coverage available to the public in plain language and submit this data to the Department of Health and Human Services (HHS), the Exchange, and the state insurance commissioner. Section 2715A of the Public Health Service (PHS) Act as added by the ACA largely extends the transparency provisions set forth in section 1311(e)(3) to non-grandfathered group health plans and health insurance issuers offering group and individual health insurance coverage. *Form Number:* CMS–10572 (OMB control number: 0938–1310); *Frequency:* Annually; *Affected Public:* Private sector (Business or Not-for-profit institutions); *Number of Respondents:* 360; *Total Annual Responses:* 360; *Total Annual Hours:* 17,160. (For policy questions regarding this collection contact Jack Reeves at 301–492–5152).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control); *Title of Information Collection:* ; *Use:* This collection of information is dedicated to Medicare beneficiaries and third party requesters (law firms or others) acting on behalf of beneficiaries that are making requests for CMS to produce Medicare beneficiary records through 5 U.S.C. 552(b) (See also 42 CFR 401.136). Currently the requests are mailed/faxed/emailed to CMS. The new online portal will allow for ease and efficiency to upload the request and required authorization, which will be quickly and securely sent directly to CMS. Additionally, with the new online portal, requesters will be able to securely submit requests electronically that contain PHI or PII; they will be advised that MyMedicare.gov/Blue Button is an online service available for beneficiaries to set up an account to access their own records and give authorization to share with third parties. This secure public online portal will be integrated with the agency's current FOIA/Privacy Act case management system to ensure a centralized location for housing, securing, tracking and processing the incoming requests (See 45 CFR 5.22 and 5.24). *Form Number:* CMS–10781 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 19,000; *Total Annual Responses:* 360; *Total Annual Hours:* 17,160. (For policy questions regarding this collection contact Hugh Gilmore at 410–786–5352).

Dated: July 20, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–15756 Filed 7–22–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1764–N]

Medicare Program; Announcement of the Advisory Panel on Hospital Outpatient Payment Meeting

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a virtual meeting of the Advisory Panel on Hospital Outpatient Payment (the Panel) for Calendar Year 2021. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services concerning the clinical integrity of the Ambulatory Payment Classification groups and their associated weights, and supervision of hospital outpatient therapeutic services. The advice provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

DATES: *Meeting date:* The virtual meeting of the Panel is scheduled for Monday, August 23, 2021, from 9:30 a.m. to 5:00 p.m. Eastern Daylight Time (EDT). The times listed in this notice are EDT and are approximate times. Consequently, the meetings may last longer or be shorter than the times listed in this notice, but would not begin before the posted time.

Deadline for presentations and comment letters: Presentations or

comment letters, and form CMS–20017 (located at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf*), must be received by 5:00 p.m. EDT, Friday, August 6, 2021. We note that form CMS–20017 must accompany each presentation or comment letter submission. Presentations and comment letters that are not received by the due date and time, or that do not include a completed form CMS–20017 are considered late or incomplete, and cannot be included on the agenda. In commenting, refer to file code CMS–1764–N.

Meeting Registration Timeframe: All presentation or comment letter speakers, including any alternates, with items on the agenda must register electronically to our Panel mailbox, *APCPanel@cms.hhs.gov* no later than 5:00 p.m. EDT, Friday, August 6, 2021. The subject of the email may state ''Agenda Speaker Registration for HOP Panel Meeting.''

ADDRESSES:

Meeting location and webinar: The meeting will be held virtually. The public may participate in this meeting by webinar, or listen-only via teleconference. Closed captioning will be available on the webinar. Teleconference dial-in and webinar information will appear on the final meeting agenda, which will be posted on our website when available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.*

News media: Press inquiries are handled through the CMS Press Office at (202) 690–6145.

Advisory committees information line: The telephone number for the Advisory Panel on Hospital Outpatient Payment Committee Hotline is (410) 786–3985.

Websites: For additional information on the Panel, including the Panel charter, and updates to the Panel's activities, we refer readers to view our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.* Information about the Panel and its membership in the Federal Advisory Committee Act (FACA) database are also located at: *https://www.facadatabase.gov.*

FOR FURTHER INFORMATION CONTACT:

Elise Barringer, Designated Federal Official (DFO) (410) 786–9222, email at: *APCPanel@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) and is allowed by section 222 of the Public Health Service Act (PHA) to consult with an expert outside Panel, such as the Advisory Panel on Hospital Outpatient Payment (the Panel), regarding the clinical integrity of the Ambulatory Payment Classification (APC) groups and relative payment weights. The Panel is governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), to set forth standards for the formation and use of advisory Panels. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the Hospital Outpatient Prospective Payment System (OPPS) for the following calendar year (CY).

II. Annual Advisory Panel Meeting

A. Meeting Agenda

The agenda for the August 23, 2021 Panel meeting will provide for discussion and comment on the following topics as designated in the Panel's Charter:

- Addressing whether procedures within an APC group are similar both clinically and in terms of resource use.
- Reconfiguring APCs.
- Evaluating APC group weights.
- Reviewing packaging the cost of items and services, including drugs and devices, into procedures and services, including the methodology for packaging and the impact of packaging the cost of those items and services on APC group structure and payment.
- Removing procedures from the inpatient only list for payment under the OPPS.
- Using claims and cost report data for Centers for Medicare & Medicaid Services (CMS) determination of APC group costs.
- Addressing other technical issues concerning APC group structure.
- Evaluating the required level of supervision for hospital outpatient services.
- OPPS APC rates for covered Ambulatory Surgical Center (ASC) procedures.

The Agenda will be posted on our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups* approximately 1 week before the meeting.

B. Meeting Information Updates

The actual meeting hours and days will be posted in the agenda. As information and updates regarding this webinar and listen-only teleconference, including the agenda, become available, they will be posted to our website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.*

C. Presentations and Comment Letters

The subject matter of any presentation and comment letter must be within the scope of the Panel as designated in the Charter. Any presentations or comments outside of the scope of the Panel will be returned or requested for amendment. Unrelated topics include, but are not limited to: The conversion factor, charge compression, revisions to the cost report, pass-through payments, correct coding, new technology applications (including supporting information/documentation), provider payment adjustments, supervision of hospital outpatient diagnostic services, and the types of practitioners that are permitted to supervise hospital outpatient services. The Panel may not recommend that services be designated as nonsurgical extended duration therapeutic services. Presentations or Comment Letters that address OPPS APC rates as they relate to covered ASC procedures are within the scope of the Panel's charter; however, ASC payment rates, ASC payment indicators, the ASC covered procedures list, or other ASC payment system matters will be considered out of scope. The Panel may use data collected or developed by entities and organizations other than Department of Health and Human Services and CMS in conducting its review. We recommend organizations submit data for CMS staff and the Panel's review. All presentations are limited to 5 minutes, regardless of the number of individuals or organizations represented by a single presentation. Presenters may use their 5 minutes to present either one or more agenda items.

In the email, all of the following information must be submitted when registering:

- Speaker's name.
- Speaker's organization or company name.
- Company or organization that the speaker is representing that submitted a presentation or comment letter that is on the agenda.
- Email addresses to which materials regarding meeting registration and instructions on connecting to the meeting may be sent.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by August 06, 2021. In addition, registration information must reflect individual-level content and not reflect an organization entry. Also, each individual may only register one person at a time (that is, one individual may not register multiple individuals at the same time).

A confirmation email will be sent upon receipt of the registration. The email will provide information to the speaker in preparation for the meeting.

Registration is only required for agenda speakers and alternates and must be submitted by the deadline specified above. We note that no registration is required for participants who plan to view the Panel meeting by webinar or listen teleconference.

Section 508 Compliance

For this meeting, we are aiming to have all presentations and comment letters available on our website. Materials on our website must be Section 508 compliant to ensure access to federal employees and members of the public with and without disabilities. We encourage presenters and commenters to reference the guidance on making documents section 508 compliant as they draft their submissions, and, whenever possible, to submit their presentations and comment letters in a 508 compliant form. Such guidance is available at: *https://www.cms.gov/research-statistics-data-and-systems/cms-information-technology/section508.*

We will review presentations and comment letters for 508 compliance and place compliant materials on our website. As resources permit, we will also convert non-compliant submissions to 508 compliant forms, and offer assistance to submitters who are making their submissions 508 compliant. All 508 compliant presentations and comment letters will be made available on the CMS website. If difficulties are encountered accessing the materials, contact the Designated Federal Official (DFO) (the DFO's address, email, and phone number are provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice).

In order to consider presentations and/or comment letters, we will need to receive the following:

1. An email copy of the presentation or comment letters sent to the DFO mailbox: *APCPanel@cms.hhs.gov.*

2. Form CMS–20017, with complete contact information that includes the names, addresses, phone numbers, and email addresses for all presenters; comment letters; and a contact person who can answer any questions and provide revisions that are requested for the presentation or comment letter. Presenters and commenter letters must clearly explain the actions that they are requesting CMS take in the appropriate section of the form. A presenter or commenter's relationship with the organization that they represent must also be clearly listed.

- The form is available through the CMS Forms website at: *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf.*
- We encourage submitters to make efforts to ensure that their presentations and comment letters are 508 compliant.

D. Formal Presentations

In addition to formal presentations (limited to 5 minutes total per presentation), there will be an opportunity during the meeting for public comments as time permits (limited to 1 minute for each individual and a total of 3 minutes per organization).

E. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our website after the meeting.

F. Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

The Panel Charter provides that the Panel may meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following calendar year. The Panel may consist of a chair and up to 15 members who are full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPS. The Panel may also include a representative of the provider with ASC expertise, who may advise CMS only on OPPS APC rates, as appropriate, impacting ASC covered procedures within the context and purview of the Panel's scope. The Secretary or a designee selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations of candidates determined to have the required expertise. For supervision deliberations, the Panel may include members that represent the interests of Critical Access Hospitals, who advise CMS only regarding the level of supervision for hospital outpatient therapeutic services. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines. The Secretary rechartered the Panel in 2020 for a 2-year period effective through November 20, 2022. The current charter is available on the CMS website at: *https://www.cms.gov/files/document/2020-hop-panel-charter.pdf.* The Panel presently consists of members and a Chair named below.

- E.L. Hambrick, M.D., J.D., CMS Chairperson
- Terry Bohlke, C.P.A., C.M.A, M.H.A., C.A.S.C
- Carmen Cooper-Oguz, P.T., D.P.T, M.B.A, C.W.S, W.C.C
- Paul Courtney, M.D.
- Peter Duffy, M.D.
- Lisa Gangarosa, M.D.
- Michael Kuettel, M.D., M.B.A, Ph.D.
- Scott Manaker, M.D., Ph.D.
- Brian Nester, D.O., M.B.A.
- Bo Gately, M.B.A.
- Matthew Wheatley, M.D., F.A.C.E.P.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 20, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–15727 Filed 7–22–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Reduction of Issuer Burden Through Technology Grant

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of funding opportunity.

SUMMARY: This notice announces the issuance of the March 10, 2021 (and amended on April 29, 2021) single-source funding opportunity titled ''Reduction of Issuer Burden Through Technology Grant'' (hereafter referred to as the ''RIBTT Grant'') available solely to the National Association of Insurance Commissioners (NAIC) to build a connection between the State Electronic Rate and Form Filing (SERFF) system, owned and operated by the NAIC, and the Health Insurance Oversight System (HIOS), which is operated by the Centers for Medicare and Medicaid Services (CMS). This connection will enable health insurance issuers to enter rate justification data into the SERFF system and then have this rate justification data automatically transfer to HIOS. Currently, health insurance issuers have to enter duplicate data into both the SERFF system and HIOS in order to maintain compliance with federal and state law in 49 states and the District of Columbia.

DATES: The project period of the award, in the amount of $250,000 to the NAIC, will be 24 months from the date of award. The tentative award date is July 29, 2021.

FOR FURTHER INFORMATION CONTACT: Jim Taing, (301) 492–4182.

SUPPLEMENTARY INFORMATION:

I. Background

The Reduction of Issuer Burden Through Technology Grant (RIBTT Grant) provides a funding source to build a connection between the SERFF system and the Unified Rate Review (URR) module of HIOS. Forty-nine states and the District of Columbia currently use the SERFF system to collect and review rate data. Building a connection between SERFF and HIOS will reduce burden on health insurance issuers and decrease the potential for data mismatches between the two systems. It will enable health insurance issuers to enter rate justification data into the SERFF system and the rate justification data will automatically transfer to HIOS. Currently, health insurance issuers have to enter duplicate data into both the SERFF system and HIOS in order to maintain compliance with applicable federal and state law. Funding under the RIBTT Grant is available to the NAIC to complete their portion of the technical changes needed in order to build such a connection between the SERFF system and HIOS.

II. Provisions of the Notice

CMS is anticipating approximately a total of $250,000 will be available for the RIBTT Grant, pending availability of funds, to the NAIC to complete their portion of the technical changes needed in order to build such a connection between the SERFF system and HIOS for the transfer of rate filing information. The NAIC may use grant funds for a variety of planning, development, testing, and implementation objectives related to the technical changes needed to build the connection between the SERFF system and HIOS. This includes, but is not limited to, hiring or contracting with information technology professionals or firms to complete the work. Pending an acceptable application and budget, the CMS will recommend awarding a single source grant to the NAIC who is uniquely qualified to complete the work requested. The NAIC is uniquely positioned to perform this work as they are the only applicant under this funding opportunity to meet the objectives of this funding opportunity as they own, operate, and maintain the SERFF system and the SERFF system is what is utilized by health insurance issuers to submit rate filing justification data in 49 states and the District of Columbia. The NAIC has built previous IT connections between their SERFF system and HIOS for the submission of Qualified Health Plan certification data between SERFF and the Plan Management module of HIOS. Funds enable NAIC to establish this new IT connection between the SERFF system and the URR module of HIOS based on the prior system architecture.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 19, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–15656 Filed 7–22–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; State Developmental Disabilities Council—Annual Program Performance Report (PPR) (OMB Control Number 0985–0033)

Correction

In notice document 2021–15025, appearing on page 37337 in the issue of Thursday, July 15, 2021 make the following correction:

On page 37337, in the first column, in the **DATES** section, on the second and third lines, ''August 30, 2021'' should read, ''August 16, 2021''.

[FR Doc. C1–2021–15025 Filed 7–22–21; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0703]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2022 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2022.

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov* or visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.* For general questions, you may also email the Center for Veterinary

Medicine (CVM) at *cvmagdufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2019 through FY 2023, the FD&C Act establishes a yearly base revenue amount and percentages for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–21(c)(2) and (3)). Beginning with FY 2021, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections (21 U.S.C. 379j–21(c)(3)(B)). The target revenue amounts for each fee category for FY 2022, are as follows: For application fees, the target revenue amount is $6,199,500; for product fees, the target revenue amount is $9,299,250; and for sponsor fees, the target revenue amount is $9,299,250.

For FY 2022, the generic new animal drug user fee rates are: $548,628 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $274,314 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $17,513 for each generic new animal drug product; $234,297 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $175,723 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $117,149 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2022 product and sponsor fees by December 31, 2021. These fees will be due by January 31, 2022. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2021, and will remain in effect through September 30, 2022. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2022

A. Statutory Fee Revenue Amounts

AGDUFA III, Title II of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2022 for all generic new animal drug user fee categories is $18,336,340 (21 U.S.C. 379j–21(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

AGDUFA III specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see 21 U.S.C. 379j–21(c)(2)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2022. The 3-year average is 2.7383 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2018	2019	2020	3-year average
Total PC&B	$2,690,678,000	$2,620,052,000	$2,875,592,000	.....
Total FTE	17,023	17,144	17,535	.....
PC&B per FTE	$158,061	$152,826	$163,992	.....
Percent Change from Previous Year	4.2206	−3.3120	7.3063	2.7383

The statute specifies that this 2.7383 percent should be multiplied by the proportion of PC&B costs to total FDA costs. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COSTS AT FDA

Fiscal year	2018	2019	2020	3-year average
Total PC&B	$2,690,678,000	$2,620,052,000	$2,875,592,000	.....
Total Costs	$5,370,935,000	$5,663,389,000	$6,039,321,000	.....
PC&B Percent	50.0970	46.2630	47.6145	47.9915

The portion of the inflation adjustment relating to payroll cost is 2.7383 percent multiplied by 47.9915 percent, or 1.3142 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual

index) for the first 3 of the preceding 4 years of available data multiplied by the average proportion of all costs other than PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years. As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018,[1] the ''Washington-Baltimore, DC–MD-VA-WV'' index was discontinued and replaced with two separate indices (*i.e.,* ''Washington-Arlington-Alexandria, DC-VA-MD-WV'' and ''Baltimore-Columbia-Towson, MD''). In order to continue applying a CPI that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, FDA is using the Washington-Arlington-Alexandria index, less food and energy, in calculating the relevant adjustment factors for FY 2020 and subsequent years. Table 3 provides the summary data for the percent change in the specified CPI for the Washington-Arlington-Alexandria area. The data from the Bureau of Labor Statistics is shown in table 3.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN WASHINGTON-ARLINGTON-ALEXANDRIA AREA CPI LESS FOOD AND ENERGY

Year	2018	2019	2020	3-year average
Annual CPI	272.414	275.841	278.437	.....
Annual Percent Change	2.0671	1.2580	0.9411	1.4221

To calculate the inflation adjustment for non-payroll costs, we multiply 1.4221 percent by the proportion of all costs other than PC&B to total FDA costs. Since 47.9915 percent was obligated for PC&B as shown in table 2, 52.0085 percent is the portion of costs other than PC&B (100 percent − 47.9915 percent = 52.0085 percent). The non-payroll adjustment is 1.4221 percent times 52.0085 percent, or 0.7396 percent.

Next, we add the payroll component (1.3142 percent) to the non-payroll component (0.7396 percent), for an inflation adjustment of 2.0538 percent for FY 2022.

AGDUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2020 (see 21 U.S.C. 379j–21(c)(2)). The inflation adjustment for FY 2022 (2.0538 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2021 (3.5847 percent), as published in the **Federal Register** on August 3, 2020 (85 FR 46647 to 46651), which equals 1.057121 (rounded) (1.020538 × 1.035847) for FY 2022. We then multiply the base revenue amount for FY 2022 ($18,336,340) by 1.057121, yielding an inflation adjusted amount of $19,383,730.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j–21(c)(3)).

To determine whether a workload adjustment applies, FDA calculates the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period that ended on September 30, 2018 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended May 31, 2021.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload, and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table the sum of the values in column 5 is calculated, reflecting a total change in workload of 49.0190 percent for FY 2022. This is the workload adjuster for FY 2022.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	5-year average (base years)	Latest 5-year average	Percent change	Weighting factor	Weighted percent change
Abbreviated Application for a Generic New Animal Drug (ANADAs)	24.0	26.6	10.8333	0.1745	1.8904
Manufacturing Supplements ANADAs	169.4	198.2	17.0012	0.2601	4.4212
Generic Investigational Study Submissions	69.2	122.8	77.4566	0.4121	31.9161
Generic Investigational Protocol Submissions	34.4	58.64	70.3488	0.1534	10.7913
FY 2022 AGDUFA III Workload Adjuster	.....	.....	.....	.....	49.0190

[1] *https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm.*

The statutory revenue amount after the inflation adjustment ($19,383,730) must now be increased by 49.0190 percent to reflect the changes in review workload (workload adjustment), for a workload and inflation-adjusted amount of $28,885,441.

D. Reduction of Workload-Based Increase by Amount of Certain Excess Collections

Under section 741(c)(3)(B) of the FD&C Act, for FYs 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections, for the second preceding fiscal year, up to the amount of the fee revenue increase for workload. The workload and inflation-adjusted amount ($28,885,441) is subtracted by the inflation adjusted amount ($19,383,730) to get the workload adjustment amount ($9,501,711). Then the excess fees collected from FY 2020 as of May 31, 2021 ($4,087,114) are subtracted from the workload adjustment amount ($9,501,711) to get a reduced workload adjustment amount of $5,414,597. Next, the reduced workload adjustment amount ($5,414,597) is added to the inflation-adjusted revenue amount ($19,383,730), for a total fee revenue target of $24,798,000 (rounded to the nearest thousand dollars).

E. FY 2022 Fee Revenue Amounts

AGDUFA III specifies that the revenue amount of $24,798,000 for FY 2022 is to be divided as follows: 25 percent, or a total of $6,199,500, is to come from application fees; 37.5 percent, or a total of $9,299,250, is to come from product fees; and 37.5 percent, or a total of $9,299,250, is to come from sponsor fees (21 U.S.C. 379j–21(b)).

III. Abbreviated Application Fee Calculations for FY 2022

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term ''abbreviated application for a generic new animal drug'' means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act (21 U.S.C. 379j–21(k)(1)). The application fees are to be set so that they will generate $6,199,500 in fee revenue for FY 2022.

To set fees for abbreviated applications for generic new animal drugs to realize $6,199,500 FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2022.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates annually. In estimating the fee revenue to be generated by generic new animal drug applications in FY 2022, FDA is assuming that the number of applications for which fees will be paid in FY 2022 will equal the average number of submissions over the 5 most recently completed fiscal years of the AGDUFA program (FY 2016–FY 2020).

Also, under AGDUFA III, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j–21(a)(1)(C)(ii)).

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 8.2 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 6.2 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 11.30 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 11.30 fee-paying generic new animal drug applications in FY 2022 (8.2 original applications paying a full fee and 6.2 applications paying a half fee).

B. Application Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated 11.30 abbreviated applications that pay the fee will generate a total of $6,199,500. To generate this amount, the fee for a generic new animal drug application will have to be $548,628 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $274,314.

IV. Generic New Animal Drug Product Fee Calculations for FY 2022

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term ''generic new animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $9,299,250 in fee revenue for FY 2022.

To set generic new animal drug product fees to realize $9,299,250, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2022. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2021, FDA estimates a total of 536 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 536 products will be subject to this fee in FY 2022.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2022, FDA is estimating that 1 percent of the products invoiced, or 5 products, will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made this estimate at 1 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 531 (536 minus 5) products will be subject to product fees in FY 2022.

B. Product Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated 531 products that pay fees will generate a total of $9,299,250. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $17,513.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2022

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee must be paid annually by each person who: (1) Is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3), respectively). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(C)). Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than 1 and fewer than 7 approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(C)). The sponsor fees are to be set so that they will generate $9,299,250 in fee revenue for FY 2022.

To set generic new animal drug sponsor fees to realize $9,299,250, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2022. FDA estimates that in FY 2022, 12 sponsors will pay 100 percent fees, 18 sponsors will pay 75 percent fees, and 30 sponsors will pay 50 percent fees. That totals the equivalent of 40.5 full sponsor fees (12 $\times$ 100 percent or 12, plus 18 $\times$ 75 percent or 13.5, plus 30 $\times$ 50 percent or 15).

FDA estimates that about 2 percent of all of these sponsors, or 0.81, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made the estimate of the percentage of sponsors that will not pay fees at 2 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 39.69 full sponsor fees (40.5 − 0.81) are likely to be paid in FY 2022.

B. Sponsor Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated equivalent of 39.69 full sponsor fees will generate a total of $9,299,250. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $234,297. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $175,723, and the fee for those paying 50 percent of the full sponsor fee will be $117,149.

VI. Fee Schedule for FY 2022

The fee rates for FY 2022 are summarized in table 5.

TABLE 5—FY 2022 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2022
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$548,628
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	274,314
Generic New Animal Drug Product Fee	17,513
100% Generic New Animal Drug Sponsor Fee.[1]	234,297
75% Generic New Animal Drug Sponsor Fee.[1]	175,723
50% Generic New Animal Drug Sponsor Fee.[1]	117,149

[1]An animal drug sponsor is subject to only one fee each fiscal year.

VII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2022. In AGDUFA III a new exemption from fees was established, as follows:

Fees will not apply to any person who not later than September 30, 2023, submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under AGDUFA based only on the submission of the supplemental abbreviated application (21 U.S.C. 379j–21(d)(2)).

VIII. Procedures for Paying FY 2022 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2022 fee established in the new fee schedule must be paid for a generic new animal drug application subject to fees under AGDUFA III that is submitted on or after October 1, 2021. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* or the *Pay.gov* payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, it is required that the invoice number or PIN is included; without the invoice number or PIN the payment may not be applied, and the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, SWIFT No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's CVM. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2021, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2022 using this fee schedule. Fees will be due by January 31, 2022. FDA will issue invoices in November 2022 for any products and sponsors subject to fees for FY 2022 that qualify for fees after the December 2021 billing.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15642 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0363]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 23, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0686. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St. North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Advertising—21 CFR Part 202

OMB Control Number 0910–0686—Extension

This information collection supports Agency regulations and associated guidance. FDA protects the public health by assuring the safety, effectiveness, and security of a wide range of products. We also help consumers get accurate, science-based information they need to use medicines appropriately and improve their health.

Section 301 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331) prohibits the misbranding of FDA-regulated products, including prescription drugs. Section 502 of the FD&C Act (21 U.S.C. 352) requires that manufacturers, packers, and distributors, or anyone acting on their behalf (firms) include certain information in human prescription drug promotional labeling and advertisements.

Our prescription drug advertising regulations in part 202 (21 CFR part 202) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the ''major statement.'' If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of the FD&C Act (21 U.S.C. 352(n) and section 201 of the FD&C Act (21 U.S.C. 321(n)), and FDA's implementing regulations at § 202.1(e).

Section 202.1(e)(6) provides for certain waivers. The waiver request must set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of § 202.1(e)(6) from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance or otherwise misleading, or otherwise violative of section 502(n) of the FD&C Act.

Under § 202.1(j)(1), a sponsor must submit advertisements to FDA for prior approval before dissemination if: (1) The sponsor or FDA has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage; (2) FDA has notified the sponsor that the information must be part of the advertisements for the drug; and (3) the sponsor has failed to present to FDA a program for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements, or if such a program has been presented to FDA but is not being followed by the sponsor.

Under § 202.1(j)(1)(iii), a sponsor must provide to FDA a program for assuring that significant new adverse information about the drug that becomes known (*i.e.,* use of drug may cause fatalities or serious damage) will be publicized promptly and adequately to the medical profession in any subsequent advertisements. Under § 202.1(j)(4), a sponsor may voluntarily submit advertisements to FDA for comment prior to publication.

While the regulations establish requirements for prescription drug advertisements, we have developed the guidance document entitled, ''Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements; Guidance for Industry'' to clarify requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human and animal prescription drugs and prescription biological products. The guidance includes recommendations that pertain to traditional print promotional labeling and advertisements (*e.g.,* journal ads, detail aids, brochures), audiovisual promotional labeling (*e.g.,* videos shown in a healthcare provider's office), broadcast advertisements (*e.g.,* television advertisements, radio advertisements), and electronic and computer-based promotions (*e.g.,* internet, social media, emails, CD–ROMs, DVDs). The guidance document was issued consistent with our Good Guidance Practice regulations in part 10.115 which provide for public comment at any time, and is available from our website at: *https://www.fda.gov/media/87202/download.*

In the **Federal Register** of April 29, 2021 (86 FR 22686), we published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, all generally supportive of FDA's drug advertising regulations; however, some commenters suggested FDA might do more to promote truthful advertising with regard to prescription drug products. We appreciate all comments. No comment suggested a revision to our current estimate for the information collection.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
CDER Regulated Products:					
202.1(e)(6); waiver request	1	1	1	12	12
202.1(j)(1); submission of advertisement	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA	59	1.85	109	20	2,180
CBER Regulated Products:					
202.1(e)(6); waiver request	1	1	1	12	12
202.1(j)(1); submission of advertisement	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA	7	2.57	18	20	360
CVM Regulated Products:					
202.1(e)(6); waiver request	1	1	1	12	12
202.1(j)(1); submission of advertisement	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA	7	1	7	20	140
Total			143		2,758

[1] There are no capital costs or operating and maintenance costs associated with this collection.

Our estimate of burden we attribute to the reporting provisions in part 202 is based on our experience with the collection and a review of Agency data.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Burden per disclosure	Total hours
202.1; ad prepared in accordance with part 202	670	111.08	74,425	400	29,770,000
202.1(j)(1); info. included re. fatalities or serious damage	1	1	1	40	40
Total			74,426		29,770,040

[1] There are no capital costs or operating and maintenance costs associated with this collection.
[2] Numbers rounded to the nearest one/one-hundredth.

Under § 202.1, advertisements for human and animal prescription drug and biological products must comply with the standards described in that section. Under § 202.1(j)(1), if information that the use of a prescription drug may cause fatalities or serious damage has not been widely publicized in the medical literature, a sponsor must include such information in the advertisements for that drug. Based on a review of Agency data we estimate an average of 29,770,040 hours is incurred annually by respondents in complying with third-party disclosure requirements for prescription drug advertising. We assume a placeholder of 1 for disclosures under § 202.1(j)(1).

TABLE 3—ESTIMATED ANNUAL DISCLOSURE BURDEN DISCUSSED IN AGENCY GUIDANCE

Information collection recommendations	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
Product name placement, size, and prominence in promotional labeling and advertisements' disclosures	715	190.3	136,069	3	408,207

The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and animal prescription drugs are specified in labeling and advertising regulations (§§ 201.10(g) and (h); 202.1(b)–(d)). Based on Agency data, we estimate that, for human and animal prescription drugs and prescription biological products, an average of 715 firms disseminate approximately 136,069 advertisements and promotional pieces each year. We assume that the burden associated with complying with the regulatory requirements discussed in the guidance would be approximately 3 hours per response.

We have adjusted our estimate upward to reflect increases in prescription drug advertisements and associated disclosures.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15648 Filed 7–22–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0387]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Content of Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling and Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 23, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control numbers for the collections of information are 0910–0856 and 0910–0857. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St. North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

I. Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers

OMB Control Number 0910–0856—Extension

This information collection supports the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations that govern drug and device labeling and prescription drug and restricted device advertising. Section 502(a) of the FD&C Act (21 U.S.C. 352(a)) specifies that a drug or device shall be deemed to be misbranded if its labeling is false or

misleading in any particular, and that labeling may be considered misleading if it fails to reveal material facts about the product being promoted, including facts that are material in light of the representations made in a promotional piece (section 201(n) of the FD&C Act (21 U.S.C. 321(n))). Similarly, under sections 201(n) and 502(n) of the FD&C Act and FDA's implementing regulations (21 CFR 202.1(e)(5)(i) and (iii)), an advertisement for a prescription drug must not be false or misleading with respect to side effects, contraindications, or effectiveness, or fail to reveal material facts about the product being advertised, including facts that are material in light of the representations made in a promotional piece. The FD&C Act also specifies that restricted device advertisements must not be false or misleading (section 502(q)(1)) and must reveal facts that are material about the product being advertised (section 201(n)).

To assist respondents with drug and device labeling requirements and prescription drug and restricted device advertising, we developed the guidance for industry entitled ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers'' (June 2018) (medical product communications guidance), available at *https://www.fda.gov/media/133619/download.* This medical product communications guidance includes recommendations that firms consider when developing ''*consistent with the FDA-required labeling* (CFL)'' presentations in their labeling and advertising materials to help ensure the presentations are not false or misleading in violation of the FD&C Act and FDA's implementing regulations. The guidance also describes FDA's thinking when examining the consistency of a firm's product communications with that product's own FDA-required labeling.

As explained in the guidance, if a firm communicates information that is not contained in its product's FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use that is different from the use or uses for which the product is legally marketed. Establishing a product's intended uses is an element in establishing certain violations under the FD&C Act and Public Health Service Act. Firms' communications about their products that are consistent with the products' FDA-required labeling but that are false or misleading may subject a firm to enforcement action under the FD&C Act. Thus, the guidance not only describes FDA's thinking on communications that are consistent with the FDA-required labeling, but also provides general recommendations intended to help firms comply with requirements in the FD&C Act and FDA's implementing regulations for conveying information that is consistent with the FDA-required labeling in a truthful and non-misleading way. The medical product communications guidance recommends that firms accurately represent in the communications any study results or other data and information that are relied upon to support a firm's CFL promotional communication. Other recommendations include the clear and prominent disclosure of aspects of study design and methodology that are material for audiences to accurately interpret the information being presented (*e.g.,* type of study, study objectives, product dosage and use regimens, control or controls used, patient population studied), as well as material limitations related to the study design, methodology, and results. Also, the guidance recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. In addition, the guidance recommends that firms disclose material contextual information from the FDA-required labeling in these communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the CFL promotional communication.

The recommendations will help ensure that health care professional and consumer audiences receive truthful information about the benefits and risks of drugs and devices in firms' CFL promotional communications and that material contextual information is included in these communications so that audiences are not misled. Accurate information helps these audiences know whether drugs or devices may be appropriate for them or their patients and know what they can expect to experience when prescribing or using these products.

In the **Federal Register** of May 10, 2021 (86 FR 24868), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; one appearing to question the effectiveness of the information collection and the other offering its support. Neither comment suggested FDA revise its estimate of the attendant information collection.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Information collection activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling	324	30	9,720	4	38,880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since our last request for OMB approval, we have made no adjustments to the currently approved burden estimate.

II. Recommendations for Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities

OMB Control Number 0910–0857—Extension

This information collection also supports implementation of section 502(a) of the FD&C Act and applicable Agency regulations. Section 502(a)(1) of the FD&C Act provides that a drug or device is deemed to be misbranded ''[i]f its labeling is false or misleading in any particular.'' Under longstanding FDA practice and FDA's statute and regulations, and under case law,

labeling encompasses more than merely the label of the drug, but extends to other written, printed, or graphic matter ''accompanying such article'' (section 201(m) of the FD&C Act; see also 21 CFR 1.3(a)). Section 502(a) of the FD&C Act also includes a provision about communication of health care economic information (HCEI) to payors through labeling or advertising. To assist respondents in this regard, we developed the guidance for industry and review staff entitled ''Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers'' (June 2018) (drug and device communications guidance), available at *https://www.fda.gov/media/133620/download.*

This drug and device communications guidance includes recommendations regarding information firms should include in HCEI for prescription drugs if they choose to disseminate such materials (HCEI materials) to payors, in accordance with section 502(a) of the FD&C Act. Specifically, if a manufacturer communicates HCEI for approved prescription drugs (including biological products that also meet the definition of *drug* under the FD&C Act and approved or cleared medical devices (collectively referred to as *medical products*)) to payors, FDA recommends that firms include in HCEI materials disseminated to payors information about: (1) Various aspects of study design and methodology of an economic analysis (*i.e.,* type of analysis, modeling technique, patient population, perspective or viewpoint, treatment comparator, time horizon, outcome measures, cost estimates, and assumptions); (2) factors that limit generalizability of an economic analysis; limitations to an economic analysis; and (3) sensitivity analyses, if applicable, to allow for informed decision making by payors.

Furthermore, FDA recommends that firms include other information when disseminating HCEI materials, as applicable, to provide a balanced and complete presentation. Such information includes a statement of the FDA-approved indication of the drug and a copy of the most current FDA-approved labeling. Under section 502(a) of the FD&C Act, firms must also include a conspicuous and prominent statement to describe any material differences between the HCEI and the FDA-approved labeling. HCEI materials should also disclose whether certain studies or data sources were omitted from an economic analysis and how the omission of those studies or data sources may alter the conclusions presented in the analysis. Moreover, FDA recommends that HCEI materials disclose important risk information associated with the approved use of the drug, and pursuant to section 502(a) of the FD&C Act, HCEI materials must disclose any additional risk information related to assumptions that vary from the approved labeling. In addition, HCEI materials should disclose potential financial or affiliation biases to the extent reasonably known by firms at the time of dissemination.

The drug and device communications guidance provides similar recommendations for HCEI materials disseminated to payors about approved or cleared devices.

If firms choose to make communications to payors about unapproved products or unapproved uses of approved or cleared products, FDA recommends that firms include a clear statement with their communications that the product or use is not approved or cleared and that the safety or effectiveness of the product or use has not been established.

In the **Federal Register** of May 10, 2021, we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received; one appearing to question the effectiveness of the information collection and the other offering its support. Neither comment suggested FDA revise its estimate of the attendant information collection.

We estimate the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved prescription drugs.	430	10.465	4,500	20	90,000
Recommended information to be included when firms choose to disseminate HCEI materials to payors about approved or cleared devices.	236	10	2,360	20	47,200
Recommended information to be included when firms choose to disseminate information about unapproved products or unapproved uses of approved or cleared products.	717	2	1,434	0.5 (30 minutes)	717
Followup information to payors regarding previously communicated information about unapproved products or unapproved uses of approved or cleared products.	359	2	718	2	1,436
Total			9,012		139,353

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have adjusted the estimate of burden we associate with the information collection recommendations in the guidance to reflect an increase of 2,000 hours and 100 responses annually.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15653 Filed 7–22–21; 8:45 am]

BILLING CODE 4161–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0739]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F-MDMB-BICA (4F-MDMB-BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is inviting interested persons to submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of seven drug substances. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Submit either electronic or written comments by August 9, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 9, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 9, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0739 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F-MDMB-BICA (4F-MDMB-BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Center for Drug Evaluation and Research, Controlled Substance Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5150, Silver Spring, MD 20993–0002, 301–796–3156, *james.hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The United States is a party to the 1971 Convention on Psychotropic Substances (Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion

may require international control or change in such control, it shall so notify the Secretary-General of the United Nations (U.N. Secretary-General) and provide the U.N. Secretary-General with information in support of its opinion.

Paragraph (d)(2)(A) of the CSA (21 U.S.C. 811) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify adding a drug or other substances to one of the schedules of the Psychotropic Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that will be considered by HHS in its preparation of the scientific and medical evaluations of the drug or substance.

II. WHO Notification

The Secretary of HHS received the following notice from WHO (nonrelevant text removed):

Ref.: C.L.20.2021

The World Health Organization (WHO) presents its compliments to Member States and Associate Members and has the pleasure of announcing that the 44th Expert Committee on Drug Dependence (ECDD) will meet from 11 to 15 October 2021, coordinated from Geneva, Switzerland. Given that WHO Expert Committee meetings are of a closed nature, this letter serves to notify Member States of the substances under review at the 44th ECDD, which are in the Annex I, attached for reference.

WHO is mandated by the 1961 and 1971 International Drug Control Conventions to make recommendations to the UN Secretary-General on the need for and level of international control of psychoactive substances based on the advice of its independent scientific advisory body, the ECDD. To assess the appropriate control of a psychoactive substance, the ECDD convenes annually to review the potential of this substance to cause dependence, abuse and harm to health, as well as any therapeutic applications. In order to perform this review and make scientific and evidence-based decisions, the ECDD conducts medical, scientific, and public health evaluations of the selected psychoactive substances using the best available information.

Although the meetings are of a closed nature, Member States are invited to contribute to the ECDD review process by joining the 44th ECDD Open Session on 11 October 2021. The Open Session will allow interested parties to learn about present and future activities of the ECDD Secretariat, and to present information concerning substances under review to the Expert Committee Registration information will be made available on the ECDD website: *https://www.who.int/medicines/access/controlled-substances/en/.*

As in the past and in line with the publication ''*Guidance on the WHO review of psychoactive substances for international control*'' (EB126/2010/REC1, Annex 6),[1] Member States can also contribute to the ECDD review process by providing accurate information concerning the substances under review in advance of the meeting. For this purpose, a questionnaire will be sent to Member States to gather country information on the legitimate use, harmful use, status of national control and potential impact of international control for each substance under evaluation.

In addition to the questionnaire, Member States are also encouraged to provide any additional relevant information (unpublished or published) on substances to be reviewed by the 44th ECDD by emailing *ecddsecretariat@who.int* with the subject ''Ref: C.L.20.2021''.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 10 June 2021

[1] *https://apps.who.int/gb/ebwha/pdf_files/EB126-REC1/B126_REC1-en.pdf#page=58.*

Annex I

44th Expert Committee on Drug Dependence (ECDD) 11–15 October 2021, Substances For Review

Critical reviews: The substances listed below have never been formally reviewed by WHO and are not currently under international control. Information was brought to WHO's attention that these substances are clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any Party. The Expert Committee will consider whether information presented during a critical review may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions.

Synthetic cannabinoid receptor agonists

1. 4F-MDMB-BICA (4F-MDMB-BUTICA)

Novel synthetic opioids

2. Brorphine
3. Metonitazene

Cathinones/stimulants

4. Eutylone (bk-EBDB)
5. BMDP (3,4-Methylenedioxy-N-benzylcathinone), benzylone

Pre-reviews: The substances listed below have been proposed for a pre-review. The purpose of a pre-review is to determine whether current information justifies an Expert Committee critical review. A pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed.

Herbal drugs

6. Kratom, mitragynine, 7-hydroxymitragynine

Medicines

7. Phenibut

FDA has verified the website addresses contained in the WHO notice, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time. Access to view the WHO questionnaire can be found at *https://www.who.int/groups/who-expert-committee-on-drug-dependence/forty-fourth-ecdd-documents.*

III. Substances Under WHO Review

4F-MDMB-BICA (4F-MDMB-BUTICA) is a synthetic cannabinoid that has been sold online and used to mimic the biological effects of tetrahydrocannabinol, the main psychoactive constituent in marijuana. Research and clinical reports have demonstrated that synthetic cannabinoids are applied onto plant material so that the material may be smoked as users attempt to obtain a euphoric and psychoactive ''high.'' Synthetic cannabinoids have been marketed under the guise of ''herbal incense,'' and promoted by drug traffickers as legal alternatives to marijuana. According to the National Forensic Laboratory Information System database, 4F-MDMB-BICA emerged in the United States in May 2020 through identification in drug seizures. Per NPS Discovery,[1] 4F-MDMB-BICA has been identified in at least 26 toxicology cases associated with postmortem and driving under the influence of drugs investigations in the United States. There are no commercial or approved medical uses for 4F-MDMB-BICA, and it is not a controlled substance under the CSA but may be considered an analogue of other Schedule I substances.

Brorphine (chemical name: 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2*H*-benzo[*d*]imidazol-2-one) is a potent synthetic opioid encountered as both a single substance of abuse and in combination with other opioid substances, such as heroin and fentanyl. The appearance of brorphine on the illicit drug market is similar to other designer drugs trafficked for their psychoactive effects. Beginning in June 2019, brorphine emerged in the United States illicit, synthetic drug market as evidenced by its identification in drug seizures. The use of brorphine has been associated with at least seven fatalities between June and July 2020 in the United States. Brorphine is not approved for medical use in the United States. On March 1, 2021, the U.S. Drug Enforcement Administration issued a

[1] *https://www.npsdiscovery.org/positivity-of-new-synthetic-cannabinoid-4f-mdmb-bica-increasing-in-u-s-as-prevalence-of-5f-mdmb-pica-wanes/.*

temporary order to control brorphine as a Schedule I substance under the CSA.

Eutylone (bk-EBDB) (chemical name: 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one) is a designer drug of the phenethylamine class. Eutylone is a synthetic cathinone with chemical structural and pharmacological similarities to Schedule I and II amphetamines and cathinones, such as to 3,4-Methylenedioxymethamphetamine, methylone, and pentylone. Eutylone emerged in the United States illicit, synthetic drug market in 2014 as evidenced by its identification in drug seizures. Other evidence indicates that eutylone, like other Schedule I synthetic cathinones, is abused for its psychoactive effects. Adverse effects associated with synthetic cathinones abuse include agitation, hypertension, tachycardia, and death. Eutylone is not approved for medical use in the United States. As a positional isomer of pentylone, eutylone is controlled in Schedule I of the CSA.

BMDP (chemical name: 3,4-Methylenedioxy-N-benzylcathinone) is a designer drug of the phenethylamine class. BMDP is a synthetic cathinone with chemical structural and pharmacological similarities to Schedule I and II amphetamines (*e.g.,* methamphetamine and 3,4-methylenedioxymethamphetamine) and cathinones (*e.g.,* methylone). Law enforcement has seen an increase in the encounters of BMDP in 2019 in the United States illicit, synthetic drug market as evidenced by its identification in drug seizures. BMDP has no commercial or approved medical uses, and it is not controlled under the CSA. However, if BMDP is found to meet the criteria outlined in Title 21 of the United States Code, section 802(32) (21 U.S.C. 802(32)), and it is intended for human consumption, it may be treated as a Schedule I controlled substance analogue for the purpose of Federal law pursuant to 21 U.S.C. 813.

Mitragynine and 7-hydroxymitragynine are the main active constituents of the plant *Mitragyna speciosa,* commonly known as kratom, an indigenous plant of Southeast Asia. Kratom is abused for its ability to produce opioid-like effects. Kratom is available in several different forms to include dried/crushed leaves, powder, capsules, tablets, liquids, and gum/resin. Kratom is an increasingly popular drug of abuse and readily available on the recreational drug market in the United States. Evidence suggests that kratom is abused individually and with other psychoactive substances. Kratom does not have an approved medical use in the United States and has not been studied as a treatment agent in the United States. Kratom has a history of being used as an opium substitute in Southeast Asia. In the United States, kratom is misused to self-treat chronic pain and opioid withdrawal symptoms. Consumption of kratom can lead to a number of health impacts, including, among others, respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom has been reported to have both narcotic and stimulant-like effects, and withdrawal symptoms may include hostility, aggression, excessive tearing, aching of muscles and bones, and jerky limb movements. Kratom is not a controlled substance under the CSA.

Phenibut (chemical name: Beta-phenyl-gamma-aminobutyric acid HCl) is a neuropsychotropic drug that is used in Russia to treat alcohol withdrawal, anxiety, insomnia, and vestibular disorders. It has anxiolytic and nootropic (cognition enhancing) effects. Phenibut acts as a gamma-aminobutyric acid (GABA)-mimetic, primarily at GABA(B) and, to some extent, at GABA(A) receptors. Phenibut is sold online as a supplement to improve cognitive function, memory, creativity in healthy persons, and used to self-medicate anxiety, insomnia, and alcohol cravings. There are reports of people taking phenibut arriving to emergency departments with agitation, intoxication, altered mental status, and withdrawal, and also reports of phenibut in toxicology urinalysis reports from a prison facility, where inmates were abusing multiple drugs, including phenibut. There is no approved medical use for phenibut in the United States, and phenibut is not a controlled substance under the CSA.

IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 11 drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late 2021. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15685 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or

diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of the FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (CDC) (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are aavailable on the internet and can be accessed from *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID–19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.* The lists that follow include Authorizations issued from February 16, 2021, through May 31, 2021, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID–19, excluding multianalyte tests: [3]

- University of Illinois Office of the Vice President for Economic Development and Innovation's covidSHIELD, issued February 24, 2021;
- Viracor Eurofins Clinical Diagnostics's Viracor SARS–CoV–2 Assay DTC, issued February 26, 2021;
- Quidel Corporation's QuickVue At-Home COVID–19 Test, issued March 1, 2021;
- Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of the Massachusetts Institute of Technology and Harvard's CRSP SARS–CoV–2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), issued March 5, 2021;
- Cue Health Inc.'s Cue COVID–19 Test for Home and Over The Counter (OTC) Use, issued March 5, 2021;
- Color Health, Inc.'s Color SARS–CoV–2 RT–LAMP Diagnostic Assay DTC, issued March 19, 2021;
- Twist Bioscience Corporation's SARS–CoV–2 NGS Assay, issued March 23, 2021;
- STS Lab Holdco's (a subsidiary of Amazon.com Services LLC), Amazon Real-Time RT–PCR Test for Detecting SARS–CoV–2, issued March 25, 2021;
- DiaSorin, Inc.'s LIAISON SARS–CoV–2 Ag, issued March 26, 2021;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID–19 Ag 2 Card, issued March 31, 2021;
- Quidel Corporation's QuickVue At-Home OTC COVID–19 Test, issued March 31, 2021;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID–19 Antigen Self Test, issued March 31, 2021;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID–19 Ag Card 2 Home Test, issued March 31, 2021;
- Thermo Fisher Scientific's Amplitude Solution with the TaqPath COVID–19 High-Throughput Combo Kit, issued April 9, 2021;
- Lucira Health, Inc.'s Lucira CHECK√IT COVID–19 Test Kit, issued April 9, 2021;
- PerkinElmer Genomics's PerkinElmer SARS–CoV–2 RT-qPCR Reagent Kit, issued April 12, 2021;
- Qorvo Biotechnologies, LLC.'s Omnia SARS–CoV–2 Antigen Test, issued April 13, 2021;
- Clinical Enterprise, Inc.'s Clinical Enterprise SARS–CoV–2 RT–PCR Assay DTC, issued April 13, 2021;
- Clinical Enterprise, Inc.'s Clinical Enterprise SARS–CoV–2 RT–PCR Assay, issued April 13, 2021;
- LGC, Biosearch Technologies' Biosearch Technologies SARS–CoV–2 Real-Time and End-Point RT–PCR Test, issued April 15, 2021;
- Synergy Diagnostic Laboratory, Inc.'s (DBA SynergyDx), SynergyDx SARS–CoV–2 RNA Test, issued April 16, 2021;
- Synergy Diagnostic Laboratory, Inc.'s (DBA SynergyDx), SynergyDx SARS–CoV–2 RNA Test DTC, issued April 16, 2021;
- Celltrion USA, Inc.'s Celltrion DiaTrust COVID–19 Ag Rapid Test, issued April 16, 2021;
- Southern California Permanente Medical Group's Kaiser Permanente High Throughput SARS–CoV–2 Assay, issued April 19, 2021;
- PathogenDx, Inc.'s DetectX-Rv, issued April 20, 2021;
- InBios International, Inc.'s SCoV–2 Ag Detect Rapid Test, issued May 6, 2021;
- Phosphorus Diagnostics LLC's Phosphorous COVID19 RT-qPCR Test DTC, issued May 17, 2021;
- Salofa Oy's Sienna-Clarity COVID–19 Antigen Rapid Test Cassette, issued May 20, 2021;
- Harvard University Clinical Laboratory's Quaeris SARS–CoV–2 Assay, issued May 21, 2021;
- Thermo Fisher Scientific Inc.'s TaqPath COVID–19 Pooling Kit, issued May 25, 2021.

FDA is hereby announcing the following Authorizations for serology tests: [4]

- Abbott Laboratories Inc.'s AdviseDx SARS–CoV–2 IgG II, issued March 1, 2021;
- Beckman Coulter, Inc.'s Access SARS–CoV–2 IgG II, issued March 22, 2021;
- Siemens Healthcare Diagnostics Inc.'s Atellica IM SARS–CoV–2 IgG (sCOVG), issued March 23, 2021;
- Symbiotica, Inc.'s COVID–19 Self-Collected Antibody Test System, issued April 5, 2021;
- Inova Diagnostics, Inc.'s QUANTA Flash SARS–CoV–2 IgG, issued April 19, 2021;
- QIAGEN, GmbH's QIAreach Anti-SARS–CoV–2 Total Test, issued May 11, 2021;
- ZEUS Scientific, Inc.'s ZEUS ELISA SARS–CoV–2 Total Antibody Test System, issued May 11, 2021;
- DiaSorin, Inc.'s LIAISON SARS–CoV–2 TrimericS IgG, issued May 19, 2021;
- NOWDiagnostics, Inc.'s ADEXUSDx COVID–19 Test, issued May 24, 2021.

FDA is hereby announcing the following Authorization for a T-cell immune response test:

- Adaptive Biotechnologies Corporation's T-Detect COVID Test, issued March 5, 2021.[5]

[3] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing COVID–19, and that the known and potential benefits of the products, when used for diagnosing COVID–19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[4] As set forth in the EUAs for these products, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing recent or prior infection with SARS–CoV–2 by identifying individuals with an adaptive immune response to the virus that causes COVID–19, and that the known and potential benefits of the products when used for such use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

[5] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the T-Detect COVID Test may be effective in diagnosing recent or prior infection with SARS–CoV–2 by identifying individuals with a T-cell immune response to the virus that causes COVID–19, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of the T-Detect COVID Test; and (3) there is no adequate, approved, and

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics: [6]

- Luminex Molecular Diagnostics, Inc.'s NxTAG Respiratory Pathogen Panel + SARS–CoV–2, issued March 3, 2021; [7]
- Abbott Molecular Inc.'s Alinity m Resp-4-Plex, issued March 4, 2021; [8]
- Becton, Dickinson and Company's (BD's) BD Veritor System for Rapid Detection of SARS–CoV–2 & Flu A+B, issued March 24, 2021; [9]
- NeuMoDx Molecular, Inc.'s NeuMoDx Flu A–B/RSV/SARS–CoV–2 Vantage Assay, issued March 25, 2021.[10]

FDA is hereby announcing the following Authorizations for other medical devices:

- GetMyDNA's GetMyDNA COVID–19 Test Home Collection Kit, issued March 9, 2021; [11]
- Color Health, Inc.'s Color COVID–19 Self-Swab Collection Kit DTC, issued March 19, 2021; [12]
- Tiger Tech Solutions, Inc.'s Tiger Tech COVID Plus Monitor, issued March 19, 2021.[13]
- Inspire Rx, LLC's Inspire Rx, LLC Portable Negative Pressure Isolation & Procedural Tent System, (referred to as the ''AerosolVE Device''), issued March 29, 2021; [14]
- J. Peter Rubin, MD, MBA, FACS at the University of Pittsburgh's Individual Biocontainment Unit (''IBU''), issued April 1, 2021; [15]

available alternative to the emergency use of the T-Detect COVID Test.

[6] There are FDA-approved/cleared tests for Influenza A virus (with subtype differentiation), and other organisms, such as Influenza B virus, Respiratory Syncytial virus (RSV) A and RSV B, Coronaviruses 229E, OC43, NL63 and HKU1, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Parainfluenza virus Types 1, 2, 3, and 4, Human Bocavirus, *Chlamydophila pneumoniae,* and *Mycoplasma pneumoniae* but there are no FDA approved/cleared multiplexed tests for simultaneous qualitative detection and differentiation of SARS–CoV–2, and these additional pathogens targeted by the products (see individual EUAs for specific other pathogens). Respiratory infections caused by the aforementioned pathogens and SARS–CoV–2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS–CoV–2, information from a test that detects and differentiates the virus that causes COVID–19 and other respiratory pathogens is needed. For example, the common influenza viruses that cause seasonal epidemics of flu, influenza A and B, is needed during the flu season that coincides with the COVID–19 pandemic.

[7] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19, through the simultaneous detection and differentiation of nucleic acids from SARS–CoV–2 and other respiratory viral and bacterial organisms and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product. The NxTAG Respiratory Pathogen Panel + SARS–CoV–2 is intended for the simultaneous detection and differentiation of nucleic acid from SARS– CoV–2 and the following organism types and subtypes: Influenza A, Influenza A H1, Influenza A H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Human Bocavirus, *Chlamydophila pneumoniae,* and/or *Mycoplasma pneumoniae.*

[8] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, influenza A virus, influenza B virus and/or RSV nucleic acids and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 through the simultaneous detection and differentiation of SARS–CoV–2, and/or influenza A virus and influenza B virus protein antigens and that the known and potential benefits of the product when used for such a use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the product may be effective in diagnosing COVID–19 and that the known and potential benefits of the product when used for diagnosing COVID–19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the GetMyDNA COVID–19 Test Home Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the GetMyDNA COVID–19 Test Home Collection Kit when used for diagnosing COVID–19, outweigh the known and potential risks of the GetMyDNA COVID–19 Test Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the GetMyDNA COVID–19 Test Home Collection Kit.

[12] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Color COVID–19 Self-Swab Collection Kit DTC may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the Color COVID–19 Self-Swab Collection Kit DTC when used for diagnosing COVID–19, outweigh the known and potential risks of the Color COVID–19 Self-Swab Collection Kit DTC; and (3) there is no adequate, approved, and available alternative to the emergency use of the Color COVID–19 Self-Swab Collection Kit DTC.

[13] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Tiger Tech COVID Plus Monitor, when used by trained personnel, may be effective at preventing exposure to and spread of SARS–CoV–2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines, and that the known and potential benefits of such product, when used as described in the Scope of Authorization of the authorization letter, outweigh the known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the Tiger Tech COVID Plus Monitor.

[14] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the AerosolVE Device may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport (when end-tidal CO_2 monitoring is not available) for a maximum duration of use of 30 minutes, of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of the AerosolVE Device for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the AerosolVE Device. During the public health emergency, it would not be feasible to require healthcare providers to limit use of the AerosolVE Device to patients with suspected or confirmed COVID–19; therefore, the authorization does not restrict use to such patients.

[15] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the IBU may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, or when performing medical procedures, or during transport of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of the IBU for

Continued

- Yale School of Public Health, Department of Epidemiology of Microbial Diseases' SalivaDirect At-Home Collection Kit, issued April 9, 2021; [16]
- Color Health, Inc.'s Color COVID–19 Self-Swab Collection Kit with Saline, issued April 14, 2021; [17]
- Prep Tech, LLC's ISOCUBE SS and ISOCUBE ONE (''ISOCUBE''), issued May 4, 2021; [18]
- Breegi Scientific, Inc.'s Negative Pressure SteriDome (NPS), issued May 6, 2021; [19]
- Phosphorus Diagnostics LLC's Pinpoint by Phosphorus COVID–19 Test Home Collection Kit DTC, issued May 17, 2021.[20]

Finally, FDA is hereby announcing an amendment to certain EUAs to allow certain authorized molecular diagnostic SARS–CoV–2 tests to be distributed and used to pool anterior nasal respiratory specimens from asymptomatic individuals as part of a serial testing program after developers submit a complete notification, including meeting required validation data, as set forth in the amendment letter. The amendment ''Amending Certain EUAs for RT–PCR Molecular-Based Diagnostic Tests to Authorize the Detection of Nucleic Acid from SARS–CoV–2 from Pooled Anterior Nasal Respiratory Specimens for Screening When Used as Part of a Serial Testing Program,'' was issued to ''Developers of Molecular-Based Diagnostic Tests Authorized for Emergency Use for Coronavirus Disease 2019 (COVID–19) as of Today's Date'' on April 20, 2021.[21]

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

such use outweigh its known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the IBU. During the public health emergency, it would not be feasible to require healthcare providers to limit the IBU use for patients with suspected or confirmed COVID–19; therefore, the authorization does not restrict use to such patients.

[16] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the SalivaDirect At-Home Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the SalivaDirect At-Home Collection Kit when used for diagnosing COVID–19, outweigh the known and potential risks of the SalivaDirect At-Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the SalivaDirect At-Home Collection Kit.

[17] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Color COVID–19 Self-Swab Collection Kit with Saline may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the Color COVID–19 Self-Swab Collection Kit with Saline when used for diagnosing COVID–19, outweigh the known and potential risks of the Color COVID–19 Self-Swab Collection Kit with Saline; and (3) there is no adequate, approved, and available alternative to the emergency use of the Color COVID–19 Self-Swab Collection Kit with Saline.

[18] As set forth in the EUA, FDA has concluded: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that ISOCUBE may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of ISOCUBE for such use outweigh its known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the ISOCUBE. During the public health emergency, it would not be feasible to require healthcare providers to limit the ISOCUBE use for patients with suspected or confirmed COVID–19; therefore, the authorization does not restrict use to such patients.

[19] As set forth in the EUA, FDA has concluded: (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the NPS may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport for a maximum duration of use of 1 hour, of patients with suspected or confirmed diagnosis of COVID–19 and that the known and potential benefits of the NPS for such use outweigh its known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the NPS. During the public health emergency, it would not be feasible to require healthcare providers to limit use of the NPS to patients with suspected or confirmed COVID–19; therefore, the authorization does not restrict use to such patients.

[20] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Pinpoint by Phosphorus COVID–19 Test Home Collection Kit DTC may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the Pinpoint by Phosphorus COVID–19 Test Home Collection Kit DTC when used for diagnosing COVID–19, outweigh the known and potential risks of the Pinpoint by Phosphorus COVID–19 Test Home Collection Kit DTC; and (3) there is no adequate, approved, and available alternative to the emergency use of the Pinpoint by Phosphorus COVID–19 Test Home Collection Kit DTC.

[21] As set forth in the amendment, FDA has concluded (1) SARS–CoV–2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus, (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized tests may be effective in diagnosing COVID–19 for the indications set forth in the appendices of the amendment letter, and that the known and potential benefits of the authorized tests when used for such use, outweigh the known and potential risks of the authorized tests included in the amendment; and (3) there are no adequate, approved, and available alternatives to the emergency use of the authorized tests included in the amendment.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6395]

Request for Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; request for applications.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications of patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the Office of Patient Affairs, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner, and is hosted by CTTI. Through the PEC, the patient community and regulators are able to discuss an array of topics regarding increasing meaningful patient engagement in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patients and patient advocates are partners in non-product specific

aspects of the medical product development and FDA review process.

DATES: Applications submitted by 11:59 p.m. Eastern time on August 23, 2021, will be considered for membership in the PEC. Incomplete applications and applications completed after the above-specified deadline will not be reviewed.

ADDRESSES: All applications should be submitted to FDA's Office of Patient Affairs in OCPP. The preferred application method is via the online submission system provided by CTTI, available at *https://duke.qualtrics.com/jfe/form/SV_eLDSvmVIXdsAdVP.* For those applicants unable to submit an application electronically, please call FDA's Office of Patient Affairs at 301–796–8460 to arrange for mail or delivery service submission. Only complete applications, as described under section IV of this document, will be considered.

FOR FURTHER INFORMATION CONTACT: Wendy Slavit, Office of the Commissioner, Office of Clinical Policy and Programs, Office of Patient Affairs, Food and Drug Administration, 301–796–8460, *PatientEngagementCollaborative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The CTTI is a public-private partnership cofounded by FDA and Duke University whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The PEC is an ongoing, collaborative forum in which the patient community and regulators discuss an array of topics regarding increasing patient engagement in medical product development and regulatory discussions at FDA. The PEC is a joint endeavor between FDA and CTTI. The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization, and membership will not constitute employment by either organization.

The Food and Drug Administration Safety and Innovation Act (Pub. L. 112–14), section 1137, entitled ''Patient Participation in Medical Product Discussions,'' added section 569C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c). This provision directs the Secretary of Health and Human Services to ''develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions.'' On November 4, 2014, FDA issued a **Federal Register** notice establishing a docket (FDA–2014–N–1698) for public commenters to submit information related to FDA's implementation of this provision. Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers. After considering the comments, FDA formed the PEC in 2018 to discuss a variety of patient engagement topics. This group is consistent with additional legislation subsequently enacted in section 3001 of the 21st Century Cures Act (Pub. L. 114–255) and section 605 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), further supporting tools for fostering patient participation in the regulatory process.

The PEC currently has 16 members. To help ensure continuity in its activities and organizational knowledge, the PEC maintains staggered membership terms. As of September 2021, eight members will complete a term and up to eight new members will be selected. The purpose of this notice is to announce that the application process for up to eight new members of the PEC is now open, and to invite and encourage applications by the submission deadline for appropriately qualified individuals.

II. Criteria for Membership

The PEC includes up to 16 diverse representatives of the patient community. Eight members from the previous application process will remain on the PEC. The current application process is to select up to eight new PEC members. Selected members will include the following: (1) Patients who have personal disease experience; (2) caregivers who support patients, such as a parent, child, partner, other family member, or friend, and who have personal disease experience through this caregiver role; and, (3) representatives from patient groups who, through their role in the patient group, have direct or indirect disease experience. Please note that for purposes of this activity, the term ''caregiver'' is not intended to include individuals who are engaged in caregiving as healthcare professionals; and the term ''patient group'' is used herein to encompass patient advocacy organizations, disease advocacy organizations, voluntary health agencies, nonprofit research foundations, and public health organizations. The ultimate goal of the application and selection process is to identify individuals who can represent a collective patient voice for their patient community.

Selection criteria include the applicant's potential to meaningfully contribute to the activities of the PEC, ability to represent and express the patient voice for his or her constituency, ability to work in a constructive manner with involved stakeholders, and understanding of the clinical research enterprise. Consideration will also be given to ensuring the PEC includes diverse perspectives and experiences, including but not limited to sociodemographic and disease experience diversity. PEC members are required to be residents of the United States and must be 18 years of age or older.

Financial and other conflicts of interest will not necessarily make applicants ineligible for membership in the PEC. However, applicants cannot be direct employees of the medical product development industry or a currently registered lobbyist for an FDA-regulated industry.

III. Responsibilities and Expectations

Working meetings of the PEC will typically be held two to four times per year, either in person (in the Washington DC area) or virtually (teleconference or webinar). Given the ongoing COVID–19 pandemic, meetings will be conducted virtually and may resume in-person when it is safe to do so. Additional meetings may be organized as needed, and currently include monthly, 1-hour teleconferences.

Reasonable accommodations will be made for members with special needs for travel or for participation in a meeting. Applications for PEC membership are encouraged from individuals of all racial, ethnic, cultural groups, sexual orientations, gender identities, with and without disabilities. Travel support will be provided as applicable.

To help ensure continuity in its activities and organizational knowledge, the PEC will maintain staggered membership terms for patient community representatives. Membership terms for new members will be 2-year appointments. Members may serve up to two terms, with the possibility of extensions.

Additional responsibilities and expectations are set forth in the PEC Framework, which should be reviewed

prior to submitting an application, available at *https://www.ctti-clinicaltrials.org/framework-cttifda-patient-engagement-collaborative.*

IV. Application Process

Any interested person may apply for membership on the PEC. To apply, go to *https://duke.qualtrics.com/jfe/form/SV_eLDSvmVIXdsAdVP.* The application process is completed online and includes answering questions to help determine eligibility for the PEC, demographic and other background questions, and four brief essay questions. Many of the demographic questions are optional. The brief essay questions, which must be answered in 500 characters or fewer (including spaces), are as follows:

- Please explain why you would have an outstanding ability to represent and express the patient voice for the disease area(s) you selected above.
- Please give a few examples of experiences that demonstrate your outstanding ability to work across stakeholders in the medical product development process.
- Please explain how you have developed a strong understanding of the medical product development process.
- Please tell us why you are interested in becoming a member of the PEC and how you would be able to contribute.

Completing the application form also requires submitting: (1) A current, complete curriculum vitae or résumé that shows relevant activities and experience (PDF format preferred) and (2) a letter of endorsement (maximum 800 words) from a patient group with which the applicant has worked closely on activities that are relevant to the PEC (PDF format preferred). The letter of endorsement should emphasize information relevant to the criteria for membership described above. The letter may address topics such as the applicant's involvement in patient advocacy activities, experiences that stimulated an interest in participating in discussions about patient engagement in medical product development and regulatory decision making, and other information that may be helpful in evaluating the applicant's qualifications as a potential member of the PEC. Only complete applications submitted by the deadline (see **DATES**) will be reviewed.

Additional information may be needed from applicants, including information relevant to understanding potential sources of conflict of interest, in which case applicants will be contacted directly.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15643 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2326]

Field Alert Report Submission: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Field Alert Report Submission: Questions and Answers.'' This guidance provides FDA's current thinking regarding the requirements for submission of field alert reports (FARs) by applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) and outlines FDA's recommendations for FAR submissions to help improve their consistency and relevancy. The guidance also addresses certain frequently asked questions about FARs. This guidance finalizes the draft guidance of the same title issued on July 19, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on July 23, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–2326 for ''Field Alert Report Submission: Questions and Answers.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mohamed Ghorab, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3141, Silver Spring, MD, 20993–0002, 240–402–8940; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Field Alert Report Submission: Questions and Answers.'' The FAR regulations found in § 314.81(b)(1) (21 CFR 314.81(b)(1)) and 21 CFR 314.98(b) establish an early warning system to help FDA fulfill its responsibility to protect patient health. Under these regulations, NDA and ANDA applicants must submit certain information to FDA about distributed drug products regulated by the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research.

The guidance addresses the FAR submission requirements and focuses on topics such as the incidents and possible/actual quality issues that require submission of a FAR, the contents of the FAR, who submits the FAR, and when, where, and how they should submit it. The guidance also addresses followup and final FARs, which are not required under § 314.81(b), and recommends their submission to inform FDA of the status of root cause investigations and corrective actions taken, if any.

This guidance finalizes the draft guidance issued on July 19, 2018 (83 FR 34142). In response to public comments, FDA made minor editorial changes and clarified that the FAR requirements apply to all products under an NDA or ANDA, including positron emission tomography drugs, designated medical gases, and combination products containing a drug constituent part. Although not the focus of this guidance, FDA notes that FAR requirements also apply to certain combination products under 21 CFR part 4, subpart B. For additional information about these products, see the guidance for industry and FDA staff ''Postmarketing Safety Reporting for Combination Products,'' available at *https://www.fda.gov/media/111788/download,* and the Postmarketing Safety Reporting for Combination Products web page at *https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.* FDA may consider whether additional adjustments are needed to guidance or FAR-related instructions for biologics license applications or device applications for combination products that contain a drug constituent part as the Agency gains experience with safety reporting for such products.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Field Report Alert Submission.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15645 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0424]

Medical Devices; Exemption From Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport; Extension of Comment Period

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice that appeared in the **Federal Register** of June 15, 2021. In the notice, FDA requested comments by August 16, 2021. The Agency is taking this action in response to a correction to the notice's docket number that appeared in the **Federal Register** of June 30, 2021, to allow interested persons time to submit comments in response to the corrected notice.

DATES: FDA is extending the comment period on the notice published June 15, 2021 (86 FR 31722). Submit either electronic or written comments by August 30, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 30, 2021. The *https://www.regulations.gov*

electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 30, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–P–0424 for ''Medical Devices; Exemption from Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Dan Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1526, Silver Spring, MD 20993–0002, 240–402–4717.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 2021, FDA published a notice with a 60-day comment period requesting comments by August 16, 2021. Comments on the notice will inform FDA's response to a petition requesting exemption from premarket notification requirements for powered patient transport, all other powered patient transport.

In the **Federal Register** of June 30, 2021, FDA corrected the docket number associated with the notice (86 FR 34770). FDA has considered the requirements associated with receipt of a petition requesting exemption from premarket notification requirements under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)). Due to the correction to the docket number, the Agency is extending the comment period for the notice, until August 30, 2021. The Agency believes that an extension allows adequate time for interested persons to submit comments from the date of the correction to the notice issued June 30, 2021, without delaying our consideration of these important issues.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15646 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1136 and FDA–2020–D–1137]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on July 23, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))). Submit written requests for single copies of these guidances to the address noted in table 1. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357, or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at *https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf*), FDA announced procedures for making available FDA guidances related to the COVID–19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID–19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID–19-related guidances. Therefore, FDA will issue COVID–19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and ''Search for FDA Guidance Documents'' (available at *https://www.fda.gov/regulatory-*

[1] Secretary of Health and Human Services, ''Determination that a Public Health Emergency Exists'' (originally issued on January 31, 2020, and subsequently renewed), available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), available at: *https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.* On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID–19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic (February 24, 2021), available at *https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic.*

information/search-fda-guidance-documents).

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID–19-related guidance, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID–19-related guidances that are posted on FDA's website.

II. Availability of COVID–19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID–19-related guidances:

TABLE 1—GUIDANCES RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA–2020–D–1136	CDER	Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency Questions and Answers (Updated May 2021).	*druginfo@fda.hhs.gov.* Please include the docket number FDA–2020–D–1136 and complete title of the guidance in the request.
FDA–2020–D–1137	CBER	Emergency Use Authorization for Vaccines to Prevent COVID–19 (Updated May 2021).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 1–800–835–4709 or 240–402–8010; email *ocod@fda.hhs.gov*.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CDER Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 2).

Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

TABLE 2—CDER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control Nos.
Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency Questions and Answers (Updated May 2021).	21 CFR 314.50, 314.94, 314.95, 314.125, 314.127; 21 CFR 601.2 and 601.20.	—Prioritization of the Review of Original ANDAs, Amendments, and Supplements. —Requests for Expedited Review of New Drug Application and Biologics License Application Prior Approval Supplements Submitted for Chemistry, Manufacturing, and Controls Changes. —Administrative Processing of Original Biologics License Applications (BLA) and New Drug Applications (NDA). —Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products. —Changes to an Approved Application: Biological Products. —Changes to an Approved NDA or ANDA; Questions and Answers. —Changes to an Approved NDA or ANDA. —CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports. —Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture. —CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports. —Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products. —Immediate Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation. —SUPAC–IR: Questions and Answers about SUPAC–IR Guidance.	0910–0001 0910–0014 0910–0338 0910–0045 0910–0139 0910–0759

TABLE 2—CDER GUIDANCES AND COLLECTIONS—Continued

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control Nos.
		—SUPAC–SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation. —SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation. —SUPAC: Manufacturing Equipment Addendum. —Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID–19 Public Health Emergency.	

B. CBER Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 3). Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

TABLE 3—CBER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control Nos.
Emergency Use Authorization for Vaccines to Prevent COVID–19 (Updated May 2021).	21 CFR 314.420 21 CFR part 312 21 CFR parts 210, 211, and 610 21 CFR part 600 21 CFR part 601	Emergency Use Authorization of Medical Products and Related Authorities.	0910–0001 0910–0014 0910–0139 0910–0308 0910–0338 0910–0595

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders.*
- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or
- *https://www.regulations.gov.*

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15649 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NINDS BRAIN Review Meeting (U01 and R01 Applications).

Date: August 12–13, 2021.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, (301) 496–9223, *mirahamed.hossain@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 20, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–15744 Filed 7–22–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Institutional Training Program (T32) Review SEP.

Date: October 25, 2021.

Time: 09:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892, (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 959 Bethesda, MD 20892, (301) 451–3398, *hayesj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, HHS)

Dated: July 19, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–15647 Filed 7–22–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services announces a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC). The ISMICC is open to the public and can be accessed via telephone or webcast only, and not in person. Agenda with call-in information will be posted on SAMHSA's website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will include information on federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED).

DATES: August 27, 2021, 1:00 p.m.–5:00 p.m. (EDT)/Open.

ADDRESSES: The meeting will be held virtually and can be accessed via Zoom.

FOR FURTHER INFORMATION CONTACT: Pamela Foote, ISMICC Designated Federal Officer, SAMHSA, 5600 Fishers Lane, 14E53C, Rockville, MD 20857; telephone: 240–276–1279; email: *pamela.foote@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in SMI and SED, research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMIs, SEDs, and advances in access to services and supports for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to SMI and SED have on public health, including public health outcomes such as: (A) Rates of suicide, suicide attempts, incidence and prevalence of SMIs, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment; (B) increased rates of employment and enrollment in educational and vocational programs; (C) quality of mental and substance use disorders treatment services; or (D) any other criteria determined by the Secretary. Finally, the ISMICC will make specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with SMI or children with SED. Not later than one (1) year after the date of enactment of the 21st Century Cures Act, and five (5) years after such date of enactment, the ISMICC shall submit a report to Congress and any other relevant federal department or agency.

II. Membership

This ISMICC consists of federal members listed below or their designees, and non-federal public members.

Federal Membership: Members include, The Secretary of Health and Human Services; The Assistant Secretary for Mental Health and Substance Use; The Attorney General; The Secretary of the Department of Veterans Affairs; The Secretary of the Department of Defense; The Secretary of the Department of Housing and Urban Development; The Secretary of the Department of Education; The Secretary of the Department of Labor; The Administrator of the Centers for Medicare and Medicaid Services; and The Commissioner of the Social Security Administration.

Non-Federal Membership: Members include, 15 non-federal public members appointed by the Secretary, representing psychologists, psychiatrists, social workers, peer support specialists, and other providers, patients, family of patients, law enforcement, the judiciary, and leading research, advocacy, or service organizations.

The ISMICC is required to meet at least twice per year.

To attend virtually, submit written or brief oral comments, or request special accommodation for persons with disabilities, contact Pamela Foote. Individuals can also register on-line at: *https://snacregister.samhsa.gov/MeetingList.aspx.*

The public comment section will be scheduled at the conclusion of the meeting. Individuals interested in submitting a comment, must notify Pamela Foote on or before August 20, 2021 via email to: *Pamela.Foote@samhsa.hhs.gov.*

Up to three minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be considered for inclusion in the official record of the meeting.

Substantive meeting information and a roster of Committee members is available at the Committee's website: *https://www.samhsa.gov/about-us/advisory-councils/meetings.*

Dated: July 16, 2021.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2021–15663 Filed 7–22–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GR21ZD01BNEEC00; OMB Control Number 1028–NEW]

Agency Information Collection Activities; Angler Participation Study

AGENCY: Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before September 21, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–NEW in the subject line of your comments. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Lucas Bair by email at *lbair@usgs.gov,* or by telephone at 928–556–7362.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: In 2019 the National Park Service (NPS) completed a plan for non-native fish management from Glen Canyon Dam to Lees Ferry and on through Grand Canyon National Park. The NPS identified specific tools for managing non-native brown trout with public and partner input, including an incentivized harvest program that offers a reward to anglers for catching and harvesting brown trout. The Glen Canyon Dam Adaptive Management Program along with its science provider, the US Geological Survey's Grand Canyon Monitoring and Research Center, is interested in understanding the participation of anglers in the brown trout incentivized harvest program. A mail-back survey will be used to collect information concerning (1) trip characteristics, (2) incentive structure and (3) opinions on river management. This collection proposes to provide data that will be used to inform the ongoing incentivized harvest program.

Title of Collection: Angler Participation Study.

OMB Control Number: 1028–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: General public and individual households.

Total Estimated Number of Annual Respondents: 800.

Total Estimated Number of Annual Responses: 400.

Estimated Completion Time per Response: We estimate the public reporting burden to be 20 minutes per completed survey response.

Total Estimated Number of Annual Burden Hours: 200.

Respondent's Obligation: Voluntary.

Frequency of Collection: One-time.

Total Estimated Annual Nonhour Burden Cost: We have not identified any nonhour burden costs associated with this collection of information.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Theodore Melis,

Deputy Center Director, Southwest Region.

[FR Doc. 2021–15713 Filed 7–22–21; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK941000.L14100000.ET0000.212]

Notice of Intent To Prepare an Environmental Assessment To Consider Opening Lands Subject to ANCSA 17(d)(1) Withdrawals to Selection Under the Alaska Native Vietnam-Era Veterans Land Allotment Program of 2019

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA), as amended; the Federal Land Policy and Management Act of 1976 (FLPMA), as amended; the Alaska National Interest Lands Conservation Act of 1980 (ANILCA), as amended; the Alaska Native Claims Settlement Act (ANCSA), as amended; and the John D. Dingell, Jr. Conservation, Management, and Recreation Act of 2019 (Dingell Act), the Bureau of Land Management (BLM) intends to prepare an Environmental Assessment (EA) to consider the effects of opening lands withdrawn pursuant to Section 17(d)(1) of ANCSA to selection by eligible individuals under the Dingell Act.

DATES: This notice initiates the public scoping process for the EA. Comments on relevant issues may be submitted in writing by September 21, 2021. The deadline to submit public comment is September 21, 2021.

ADDRESSES: You may submit comments on issues related to the proposed project by any of the following methods:

- *ePlanning Website: https://eplanning.blm.gov/eplanning-ui/project/2014748/510.*
- *Mail:* 222 W. 7th Avenue, Stop #13, Anchorage, Alaska 99513.

• More details and instructions for submitting public comment can be found on the BLM ePlanning website at *https://eplanning.blm.gov/eplanning-ui/project/2014748/510.*

Documents pertinent to this proposal may be examined at the ePlanning website.

FOR FURTHER INFORMATION CONTACT: Serena Sweet at (907) 271–4534, or by email at *ssweet@blm.gov* on questions specific to NEPA, and Paul Krabacher at (907) 271–5681, or by email at *pkrabach@blm.gov,* on questions specific to the Native Vietnam-Era Veterans Land Allotment Program of 2019. People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Public Land Order (PLO) 7899, addressing lands in the Kobuk-Seward Peninsula planning area, was signed on January 11, 2021, and published in the **Federal Register** on January 19, 2021 (86 FR 5236). PLOs 7900, 7901, 7902, and 7903—addressing lands in the Ring of Fire, Bay, Bering Sea-Western Interior, and East Alaska planning areas respectively—were signed on January 15 and 16, 2021, but were never published in the **Federal Register** and therefore do not have an opening date. The Department extended the opening order for PLO 7899 by 60 days on February 18, 2021, to provide an opportunity to review the decisions and ensure the orderly management of the public lands (86 FR 10131). Subsequently, certain procedural and legal defects were identified in the decision-making process for these PLOs, including insufficient analysis under NEPA, failure to follow section 106 of the National Historic Preservation Act (NHPA), and possible failure to adequately evaluate impacts under section 7 of the Endangered Species Act (ESA). Due to these deficiencies, on April 16, 2021, the Department—relying on inherent authority to revisit decisions based on identified legal errors—delayed the opening of lands under PLO 7899 and the publication of PLOs 7900, 7901, 7902, and 7903 for up to two years.

In the meantime, the BLM has committed to undertaking a process to update the NEPA analysis for these decisions, comply with the consent requirements of Section 204(i) of FLPMA, and complete appropriate consultation under Section 106 of the NHPA, Section 7 of the ESA, and Section 810 of ANILCA in order to ensure that any decision to open some or all of the lands under reconsideration for selection under the Alaska Native Vietnam-Era Veterans Land Allotment Program is adequately supported under the law and, once conveyed, there are no questions about ownership of Alaska Native Veterans' allotments.

The Alaska Native Vietnam-Era Veterans Land Allotment Program was established by Section 1119 of the Dingell Act. Through this program, the BLM can provide eligible individuals the opportunity to select an allotment of up to 160 acres from vacant, unappropriated, and unreserved Federal lands in Alaska, or lands selected by the State of Alaska or Alaska Native corporations if that entity agrees to relinquish that portion of their selection. By law, lands will be available for selection only for a period of five years, which began when the regulations became effective on December 28, 2020, and continues through December 29, 2025. For more information on the Alaska Native Vietnam-Era Veterans Land Allotment Program, please visit *https://www.blm.gov/programs/lands-and-realty/regional-information/alaska/land-transfer/ak-native-allotment-act/alaska-native-vietnam-veterans-land-allotment.*

Currently, approximately 1.6 million acres of BLM-administered land in Alaska is available for selection by Alaska Native Veterans, including lands selected by the State of Alaska and Alaska Native Corporations. The areas subject to this review would—if opened for selection under the Alaska Native Vietnam-Era Veterans Land Allotment Program—make available up to 28 million additional acres of lands within the Kobuk-Seward Peninsula, Ring of Fire, Bay, Bering Sea-Western Interior, and East Alaska planning areas.

Because the Dingell Act allows eligible individuals to select lands for only a limited period, and consistent with the Congressional intent that the Alaska Native Vietnam-Era Veterans Land Allotment Program quickly convey allotments to eligible individuals, the BLM will hold any applications for lands covered by PLOs 7900, 7901, 7902, and 7903 within the Kobuk-Seward Peninsula, Bay, Ring of Fire, Bering Sea-Western Interior, and East Alaska planning areas while the agency completes the EA to consider opening the lands for selection. All complete applications for lands within those planning areas will be considered as simultaneously filed at the time that any lands covered by those applications are opened to selection. If the BLM receives applications for an allotment within these lands, the agency will send a letter acknowledging receipt and notifying the applicant that all valid applications received at or prior to 8 a.m. Alaska Time on April 16, 2023, or the time that the lands covered by the applications are opened to selection, would be considered as simultaneously filed at that time. If the lands selected are not made available at the end of this process, the BLM will provide the applicant notice and they will have 60 days to make a substitute selection.

The input of Alaska Native Tribes is of critical importance to this EA. Therefore, the BLM has already held a series of government-to-government consultations with Tribes and a consultation meeting with Alaska Native corporations. During the planning process, the BLM will continue to consult with potentially affected Federally recognized Tribes on a government-to-government basis, and with affected Alaska Native corporations in accordance with Executive Order 13175 and other policies. Native concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given appropriate consideration. We respectfully request participation in consultation by these Alaska Native entities to receive their views and recommendations on lands to be opened for selection by eligible individuals. The BLM anticipates holding additional informational meetings and will also hold individual consultation meetings if requested.

The BLM will utilize and coordinate the NEPA process to help fulfill the public involvement process under the NHPA, including as provided in 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources. Federal, State, and local agencies, along with Tribes and other stakeholders that may be interested in or affected by the proposed opening of lands withdrawn by Section 17(d)(1) of ANCSA to selection of allotments for the Alaska Native Vietnam-Era Veterans Land Allotment Program, are invited to participate in the scoping process and, if eligible, may request or be asked by the BLM to participate in the development of the EA as cooperating agencies. Potentially affected Tribes will receive a letter initiating consultation under Section 106 of the NHPA in the coming weeks and the BLM will work

with consulting parties to schedule consultation meetings.

The BLM is seeking public comments on issues, planning criteria, concerns, potential impacts, alternatives, and mitigation measures that should be considered in the analysis. Substantive comments will be used to prepare an EA. Additional opportunities, for public participation will be available upon publication of the draft EA.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Chad Padgett,

State Director, Alaska.

[FR Doc. 2021–15726 Filed 7–22–21; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[EEJJ000000 212E1700D2 ET1EE0000.EIS000]

Programmatic Environmental Impact Statement for Oil and Gas Decommissioning Activities on the Pacific Outer Continental Shelf

AGENCY: Bureau of Safety and Environmental Enforcement (BSEE), Interior.

ACTION: Notice of intent (NOI) to prepare a Programmatic Environmental Impact Statement (PEIS).

SUMMARY: Consistent with the regulations implementing the National Environmental Policy Act (NEPA), BSEE intends to prepare a PEIS to inform future decisions on applications for the decommissioning of oil and gas pipelines, platforms, and other facilities offshore of Southern California on the Pacific Outer Continental Shelf (OCS). The Bureau of Ocean Energy Management (BOEM) is assisting BSEE in the preparation of this environmental analysis.

DATES: BSEE requests comments concerning the scope of the analysis, identifying potential alternatives, significant issues for analysis (or those to be eliminated as insignificant), and potentially relevant information, studies, and analyses to be considered. All comments must be received by September 7, 2021. The draft PEIS is tentatively scheduled for publication in February 2022, followed by a 45-day public comment period. The final PEIS is tentatively scheduled for publication in June 2022, followed by a programmatic record of decision (ROD) no sooner than 30 days after publication of the final PEIS.

ADDRESSES: Comments may be submitted in writing or through *www.regulations.gov.* If in written form, comments may be delivered by hand or by mail, enclosed in an envelope labeled, ''Pacific Decommissioning'' and addressed to Richard Yarde, Regional Supervisor, Office of Environment, BOEM Pacific Region, 760 Paseo Camarillo, Suite 102, Camarillo, CA, 93010. Comments may also be submitted online through the regulations.gov web portal: Navigate to *http://www.regulations.gov* and search for Docket No. BOEM–2021–0043. Click on the ''Comment Now!'' button to the right of the document link. Enter your information and comment, then click ''Submit.''

FOR FURTHER INFORMATION CONTACT: For information on the PEIS, contact Richard Yarde, Regional Supervisor, Office of Environment, at *richard.yarde@boem.gov* or 805–384–6379.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for the Proposed Action

Oil and gas lessees, owners of operating rights, and holders of rights-of-way must decommission all OCS wells, platforms, other facilities, and pipelines, and clear the seafloor of all obstructions, in compliance with regulatory requirements principally located at 30 CFR part 250 Subpart Q. There are currently 23 oil and gas platforms and associated wells, facilities, and pipelines on the OCS offshore Southern California that were installed between the late 1960s and early 1990s and that will eventually need to be decommissioned. Lessees and owners of operating rights and holders of rights-of-way must first apply for and obtain approval from the appropriate BSEE District Manager or Regional Supervisor before decommissioning platforms, pipelines, and facilities. 30 CFR 250.1703–250.1704. Well abandonment activities are reviewed and completed prior to removal of platforms, pipelines, and other facilities, and are therefore not included within the scope of this PEIS. BSEE reviews decommissioning applications to ensure compliance with applicable regulatory standards and for safety and protection of other OCS uses and the environment. The purpose and need for this PEIS is to support future Federal review of and action on decommissioning applications for platforms, pipelines, and other facilities offshore Southern California on the Pacific OCS. Currently, eight oil and gas platforms on the OCS offshore Southern California, near Point Conception and in the Santa Barbara Channel, no longer produce oil and gas and are located on terminated leases that no longer allow resumption of production. BSEE expects to receive decommissioning applications for these platforms and associated pipelines and other facilities in the near term. It is currently unknown when decommissioning may be initiated for the remaining 15 platforms, though by regulation an initial platform removal application must be submitted for Pacific OCS facilities at least two years before production is projected to cease.

Preliminary Proposed Action and Alternatives

BSEE expects to analyze three alternatives in the PEIS: Complete Removal of platforms and associated facilities and pipelines (Preliminary Proposed Action); Partial Removal of platforms and any associated facilities and pipelines; and No Action. Each alternative is briefly described below. The action alternatives contain a number of overlapping elements. For example, a particular type of cutting tool might be used in either complete removal or partial removal, with no difference in the activity or the expected impacts. In these instances analysis of the options may be included as part of the Proposed Action only.

Alternative 1—Complete Removal (the Preliminary Proposed Action). The Preliminary Proposed Action is to authorize applications for complete removal of platforms and other facilities, decommissioning of all pipelines by removal, and clearing the seafloor of all obstructions created by the lease or right-of-way operations, as described in 30 CFR part 250 Subpart Q. These activities must be completed in a manner that is safe, does not unreasonably interfere with other uses of the OCS, and does not cause undue or serious harm to the environment.

Both the Proposed Action and Partial Removal alternative would consider

several decommissioning tools and techniques that might be proposed for use in future decommissioning projects. Some of the tools and techniques that BSEE expects to consider include the use of mechanical, hydraulic, laser, explosive, or other tools for the severance of structures; different types and sizes of vessels; various methods of excavation around the jacket to facilitate removal; and the possibility of reefing some parts of the structure either nearby or at an alternative reefing site on the OCS.

Alternative 2—Partial Removal. Partial removal of platforms and other facilities may include removing the top of the platform jacket to a level that is at least 85 feet below the waterline while leaving the lower portions of the jacket intact. This alternative may include decommissioning pipelines in place once they have been properly prepared in accordance with 30 CFR 250.1750–250.1751.

Alternative 3—No Action. The PEIS will also evaluate a No Action alternative, which means no Federal action would be taken on decommissioning applications. This alternative would not meet the purpose and need of the Proposed Action or legal obligations of the bureau. However, this alternative is included as a comparison that helps in understanding the Proposed Action and the other action alternative and their associated impacts.

Summary of Expected Impacts

Potential environmental impacts may result from platform or other facility or pipeline removal, marine vessel operations, and, potentially, any objects or structures left in place. The primary resources potentially impacted may include air quality, water quality, wildlife habitat, benthic resources, fish, and marine mammals. Major socio-economic considerations may include commercial and recreational fishing, vessel space-use issues, and changes to the viewshed during and after decommissioning activities. Factors that may produce impacts include air emissions, water pollution, noise, habitat alteration, and turbidity.

Anticipated Permits and Authorizations

Neither the PEIS nor the resulting programmatic ROD will authorize any specific activities or approve any individual applications. The PEIS and ROD will provide a programmatic environmental analysis and framework to support future decisionmaking on individual decommissioning applications. When decommissioning applications are submitted to BSEE, the site-specific characteristics of the project will be evaluated at that time by preparing additional environmental analyses that may tier to this PEIS. Based on the site-specific applications and evaluations, BSEE may then reach a site-specific NEPA determination and approve, approve with conditions, or deny individual decommissioning applications. This PEIS will inform future BSEE decisions on various decommissioning activities, but will not independently approve or authorize any applications or permits and therefore neither the PEIS nor ROD will constitute final agency action.

Potential future BSEE decisions that may rely on this PEIS include decisions on initial platform removal applications (30 CFR 250.1726), decisions on final applications to remove a platform or other facility (30 CFR 250.1727), decisions on pipeline decommissioning applications (30 CFR 250.1750 and 250.1752), decisions on departure requests (30 CFR 250.142 and 250.1730), and decisions on alternate procedures or equipment requests (30 CFR 250.141). The decommissioning process may also require permits and approvals from other agencies, potentially including the U.S. Army Corps of Engineers, the U.S. Coast Guard, and the California Coastal Commission, among others. Further, decommissioning of OCS facilities may proceed concurrently with decommissioning activities for related oil and gas infrastructure located in State waters and onshore, and therefore may involve additional oversight and approvals from the State of California.

Schedule for the Decision-Making Process

The draft PEIS is tentatively scheduled for publication in February 2022. The final PEIS is tentatively scheduled for publication in June 2022, with a ROD to follow no sooner than 30 days later.

The timing of regulatory decisions that BSEE must make on future decommissioning applications is uncertain. BSEE could receive applications for decommissioning at any time over the next several years, with actual decommissioning occurring any time into subsequent years and possibly decades. The intent of this programmatic analysis is to analyze broad commonalities among expected future decommissioning projects and to provide a forum for early consideration of programmatic impacts and policy choices. BSEE expects that once decommissioning applications are received, additional analyses will then be tiered to this PEIS (including any supplemental PEISs, as appropriate) and will consider the site-specific circumstances present at that time.

Public Scoping Process

This NOI initiates the scoping process, which guides the development of the PEIS. The scope of the PEIS is the range of issues, alternatives, impacts, and mitigation measures to be considered. Scoping will help focus the analysis in the PEIS on the significant issues and alternatives and will eliminate from detailed consideration any issues that are insignificant or irrelevant. After the publication of this NOI in the **Federal Register**, the public will have 45 days to submit comments; the deadline to submit comments is identified in the **DATES** section above. The methods to submit comments are provided in the **ADDRESSES** section above. Supplemental information to assist the public in providing scoping comments is available at *www.boem.gov/Pacific-decomm-PEIS*. This supplemental information includes maps of the relevant geographic area, a description of the environmental setting, and further details about existing oil and gas infrastructure.

Please include your name and address as part of your comment. BSEE makes all comments, including the names, addresses, and other personally identifiable information included in the comment, available for public review online and during regular business hours. Individuals may request that BSEE withhold their names or addresses from the public record; however, BSEE cannot guarantee that it will be able to do so. In order for BSEE to withhold from disclosure your personally identifiable information, you must identify any information contained in your comments that, if released, would constitute a clearly unwarranted invasion of your privacy. You also must briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. All submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses will be made available for public inspection in their entirety.

NEPA Cooperating Agencies

BSEE invites other Federal agencies and State, federally recognized tribes (Tribes), and local governments to consider becoming cooperating agencies in the preparation of this PEIS. The Council on Environmental Quality (CEQ) NEPA regulations specify that qualified agencies and governments are those with ''jurisdiction by law or

special expertise.'' 40 CFR 1501.7(h). Potential cooperating agencies should consider their authority and capacity to assume the responsibilities of a cooperating agency and should be aware that an agency's role in the environmental analysis neither enlarges nor diminishes the final decision-making authority of any other agency involved in the NEPA process.

Upon request, BSEE will provide potential cooperating agencies with a written summary of expectations for cooperating agencies, including schedules, milestones, responsibilities, scope and detail of cooperating agencies' contributions, and availability of pre-decisional information. BSEE anticipates this summary will form the basis for a memorandum of agreement between BSEE and any cooperating agency outside the Department of the Interior. Agencies also should consider the factors for determining cooperating agency status in CEQ's memorandum entitled, ''Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act,'' dated January 30, 2002. This document is available on the internet at: *https://www.energy.gov/nepa/downloads/cooperating-agencies-implementing-procedural-requirements-national-environmental.* BSEE, as the lead agency, will not provide financial assistance to cooperating agencies. Even if a governmental entity is not a cooperating agency, it will have opportunities to provide information and comments to BSEE during the public input stages of the NEPA process.

National Historic Preservation Act (NHPA) Consulting Parties

Certain individuals and organizations with a demonstrated interest in the Preliminary Proposed Action or alternatives may request to participate as NHPA consulting parties under 36 CFR 800.2(c)(5) based on their legal or economic stake in historic properties affected by the Preliminary Proposed Action or its alternatives. Additionally, the same provision allows those with concerns about the Preliminary Proposed Action's effect on historic properties to request to be consulting parties. Parallel with its NEPA analyses, BSEE will compile a list of potential consulting parties and, in writing, invite these potential participants to become consulting parties. To become a consulting party, those invited must respond in writing. Interested individuals or organizations that do not receive an invitation may request to be consulting parties by writing to BSEE via the means provided in the **ADDRESSES** section above. BSEE will determine which interested parties should be consulting parties.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Proposed Action

BSEE invites interested Federal and State agencies, Tribes, organizations and enterprises, and individuals to submit comments or suggestions that assist in identifying potentially significant environmental issues, relevant information, alternatives to the Proposed Action, and determining the scope of the Proposed Action.

Decision Maker

The decision maker for approving Pacific OCS decommissioning activities is the BSEE Pacific OCS Regional Director. The responsible official for the environmental analysis process and development of this PEIS is the BSEE Director.

Nature of Future Decisions To Be Made

The BSEE Pacific OCS Regional Director will render decisions regarding decommissioning applications for oil and gas platforms, pipelines, and other facilities and associated infrastructure on the OCS offshore Southern California in accordance with the applicable implementing regulations of the Outer Continental Shelf Lands Act (OCSLA), 30 CFR part 250 Subpart Q—Decommissioning Activities. Potential future decisions include approvals for initial platform removal applications, final applications to remove a platform or other facility, applications to decommission pipelines, and the granting of departures or alternate procedures or equipment.

Scott Mabry,

Acting Director, Bureau of Safety and Environmental Enforcement, Associate Director for Administration.

[FR Doc. 2021–15723 Filed 7–22–21; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–528–529 and 731–TA–1264–1268 (Review)]

Uncoated Paper From Australia, Brazil, China, Indonesia, and Portugal; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty orders on uncoated paper from Australia, Brazil, China, Indonesia, and Portugal and the countervailing duty orders on uncoated paper from China and Indonesia would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: July 19, 2021.

FOR FURTHER INFORMATION CONTACT: Caitlyn Hendricks (202–205–2058), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On May 7, 2021, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (86 FR 27650, May 21, 2021); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of these reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and

addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the reviews will be placed in the nonpublic record on October 28, 2021, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.— The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on November 18, 2021. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before November 12, 2021. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on November 15, 2021. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is November 8, 2021. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is November 30, 2021. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before November 30, 2021. On December 22, 2021, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before December 30, 2021, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C.1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 19, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–15670 Filed 7–22–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB 1140–0022]

Agency Information Collection Activities; Proposed eCollection of eComments Requested; Extension Without Change of a Currently Approved Collection; Federal Explosives License/Permit (FEL) Renewal Application—ATF Form 5400.14/5400.15, Part III

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until September 21, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Shawn Stevens, Federal Explosives

Licensing Center, either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *Shawn.Stevens@atf.gov,* or by telephone at 304–616–4400.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension without change of a currently approved collection.

2. *The Title of the Form/Collection:* Federal Explosives License/Permit (FEL) Renewal Application.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 5400.14/5400.15, Part III.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): Individuals or households.

Abstract: Explosives licensees and permittees must file the Federal Explosives License/Permit (FEL) Renewal Application—ATF Form 5400.14/5400.15, Part III to maintain a valid license or permit, to continue engaging in the explosives material business, and/or transporting or buying explosives material in interstate commerce.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 2,500 respondents will use the form annually, and it will take each respondent approximately 20 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 825 hours, which is equal to 2,500 (# of respondents) * .33 (20 minutes).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Mail Stop 3E.405A, Washington, DC 20530.

Dated: July 20, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–15715 Filed 7–22–21; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Danfoss A/S, et al. Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Danfoss A/S and Eaton Corporation plc,* Civil Action No. 1:21–cv–1880–CJN. On July 14, 2021, the United States filed a Complaint alleging that Danfoss's proposed acquisition of Eaton Corporation plc's hydraulics business would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires Danfoss to divest three Danfoss hydraulic orbital motor and hydraulic steering unit manufacturing facilities and from Eaton two orbital motor production lines and one hydraulic steering unit production line.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be submitted in English and directed to Jay Owen, Acting Chief, Defense, Industrials, and Aerospace Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 8700, Washington, DC 20530 (email address: *jay.owen@usdoj.gov*).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

United States District Court for the District of Columbia

United States of America, U.S. Department of Justice, Antitrust Division, 450 Fifth Street NW, Suite 8700, Washington, DC 20530, *Plaintiff* v. *Eaton Corporation plc,* Eaton House, 30 Pembroke Road, Dublin 4, Ireland and Danfoss A/S, Nordborgvej 81, DK–6430v Nordborg, Denmark, *Defendants.*

Civil Action No.: 1:21–cv–1880–CJN

Complaint

The United States of America (''United States''), acting under the direction of the Attorney General of the United States, brings this civil antitrust action against Defendants Eaton Corporation plc (''Eaton'') and Danfoss A/S (''Danfoss'') to enjoin Danfoss's proposed acquisition of Eaton's hydraulics business. The United States complains and alleges as follows:

I. Nature of the Action

1. Pursuant to a Transaction Agreement dated January 21, 2020, Danfoss intends to acquire Eaton's hydraulics business for approximately $3.3 billion. The hydraulic power components that Danfoss and Eaton manufacture make it possible to steer, propel, and operate equipment used to pave roads, harvest produce, construct buildings, and perform other heavy industrial and agricultural tasks across the United States every day.

2. Danfoss and Eaton are two of only three suppliers of hydraulic orbital motors (''orbital motors'') and hydraulic steering units (''steering units'') used in tractors, wheel loaders, lifts, and other types of mobile off-road equipment in the United States. Orbital motors, also

called ''low-speed, high-torque'' motors, are a low-cost way to move heavy loads in a slow, and thus controlled, way. Steering units direct hydraulic fluid in response to commands from equipment operators and are necessary for any hydraulic steering system to function. Three of every four orbital motors and four of every five steering units purchased in the United States are supplied by either Danfoss or Eaton.

3. Competition between Danfoss and Eaton has driven prices down and spurred the production of new and better orbital motors and steering units. The proposed merger would eliminate this competition, leading to higher prices, lower quality, and diminished innovation.

4. As a result, the proposed acquisition would substantially lessen competition in the market for the design, manufacture, and sale of orbital motors and steering units for mobile off-road equipment in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

II. Defendants and the Transaction

5. Danfoss is a global corporation headquartered in Nordborg, Denmark that specializes in the manufacturing of components and engineering technologies for, *inter alia,* hydraulics for off-road machinery. Danfoss's Power Solutions division produces hydraulic pumps, motors, valves and steering solutions, as well as electronic components, software, motors, and converters. The Power Solutions division accounted for 35% of Danfoss's €6.3 billion in revenue in 2019.

6. Eaton is a global corporation headquartered in Dublin, Ireland that focuses on power management solutions for electrical, hydraulics, aerospace, and vehicle applications. Eaton Hydraulics, based in Eden Prairie, Minnesota, consists of a Fluid Conveyance Division that sells hoses and other fluid conveyance products and a Power & Motion Controls Division offering hydraulic motors, power units, valves, and steering units. The Power & Motion Controls division had sales of $2.2 billion in 2019.

7. On January 21, 2020, Danfoss and Eaton signed an agreement under which Danfoss will acquire Eaton's hydraulics business in exchange for $3.3 billion.

III. Jurisdiction and Venue

8. The United States brings this action under Section 15 of the Clayton Act, 15 U.S.C. 25, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

9. Defendants design, manufacture, and sell orbital motors and steering units for mobile off-road equipment throughout the United States, and their activities in these areas substantially affect interstate commerce. This Court therefore has subject matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

10. Defendants have consented to venue and personal jurisdiction in this judicial district. Venue is therefore proper in this district under Section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391(b) and (c).

IV. Industry Background

A. Hydraulic Systems

11. Most heavy industrial and agricultural operations rely on specialized equipment to perform work ''off-road'' (*e.g.,* in a construction site, a field, a forest, a mine, or on a golf course). The predominant drive technology for this equipment is a hydraulic system, which uses hydraulic fluid to generate power.

12. The basic architecture of a hydraulic system includes a reservoir for hydraulic fluid; a pump to move that fluid; valves to control the liquid in various ways (*e.g.,* pressure, flow, or direction); a motor to convert hydraulic pressure into mechanical energy; and components that accomplish the intended task, such as cylinders.

13. Mobile off-road equipment often has multiple hydraulic systems. Each system serves one of three functions: To carry out the steering commands given by a driver, to propel equipment forward, or to make the equipment perform its intended work function (*e.g.,* to operate the forks on a forklift or raise a scissor lift's platform).

14. Original Equipment Manufacturers (''OEMs'') of mobile off-road equipment select components of hydraulic systems individually, considering the performance requirements of the equipment at issue, price, and the space available to house the components selected. To determine components for a new platform, OEMs may solicit bids, seek the services of a distributor, collaborate with a preferred provider, or use in-house engineers as experts.

B. Orbital Motors

15. While all hydraulic motors turn hydraulic pressure into mechanical energy, there are different designs that can be used for mobile equipment: Gear motors, orbital motors, vane motors, and piston motors. Each design presents a different value proposition in terms of power, pressure, fluid displacement, torque, and rotational speed. OEMs consider each of these performance characteristics, as well as price and physical size, when selecting a motor to be used in a particular hydraulic system.

16. There is a direct relationship between a motor's power metrics and its price. In addition to being more expensive, a motor that is more powerful than necessary for the job has less operating efficiency. Thus, OEMs prefer products that meet, but do not exceed, their desired performance specifications. Once selected, it is difficult and expensive for an OEM to switch motor designs because of the need to retrofit the equipment to the new motor.

17. Orbital motors have a rotating gear design consisting of an external gear ring and an inner gear star. When the internal gear star rotates in a planetary-type movement, fluid that has been inserted by a pump is displaced between every gear tooth. The result is a high torque output at a low rotational speed. For this reason, orbital motors are also referred to as ''low- speed, high torque'' motors.

18. Orbital motors are in the ''low-to-medium'' power category of motors, generating fewer than 100 kilowatts of power. However, an orbital motor is efficient and generates high output levels of torque at low rotational speeds, which makes it easier to control the movement of heavy loads. Orbital motors are also uniquely attractive to OEMs because they come in a standard compact size, which OEMs can count on when designing mobile off-road equipment.

19. Because orbital motors are more commoditized and thus less expensive than other motors that produce similar amounts of torque, they are considered a ''workhorse'' motor for many OEMs that design mobile off-road equipment, and can be used for the ''work'' or ''propel'' functions for a long list of mobile off-road equipment, including potato harvesters, wheel loaders, skid steer loaders, aerial lifts, asphalt pavers, rollers, salt spreaders, harvesters, and street sweepers.

20. In contrast to orbital motors, piston motors are higher powered, higher priced, larger, and often inefficient for an application that is appropriate for an orbital motor. Similarly, gear and vane motors fail to meet an orbital motor's performance metrics for torque.

C. Hydraulic Steering Units

21. An OEM designing a power steering system for mobile off-road equipment can choose from three different steering technologies:

Hydraulic, electrohydraulic, and electric. Hydraulic steering systems—by far the most common technology used in off-road equipment—use commands from a driver to turn a vehicle's wheels using hydraulic fluid. Electrohydraulic steering systems build on hydraulic steering systems by adding electronically-controlled components that make steering with a joystick or GPS-guided steering function possible. Electric steering does not require hydraulics components and instead generates the power assist needed for steering through electric motors.

22. Hydraulic steering systems move pressurized hydraulic fluid through a circuit to control cylinders connected to the wheels of mobile off-road equipment. The piece of a hydraulic steering system that determines the direction that the fluid moves and provides pressure control is called a steering unit.

23. All hydraulic steering systems—even those with some electronic components—require a steering unit. If an OEM wished to design around a steering unit for mobile off-road equipment, it would have to shift the entirety of the steering system from hydraulic technology to the more expensive electric technology.

V. The Relevant Markets Threatened by the Acquisition

A. Relevant Product Markets

24. An OEM in need of an orbital motor's performance characteristics for a mobile off-road vehicle design would not simply substitute an alternative motor technology. No other motor offers the same combination of (1) efficiency (*i.e.,* operating power necessary for the intended use), (2) torque output, and (3) low price. Vane and gear motors do not meet the torque output performance metrics of an orbital motor, and piston and electric motors are more expensive and less efficient than an orbital motor. In order for a customer to switch to any of these alternative technologies, that customer would need to downgrade its performance expectations, engage in a costly redesign, or spend significantly more money.

25. Because of these factors, in the event of a small but significant increase in price by a hypothetical monopolist of orbital motors, substitution away from orbital motors would be insufficient to render the price increase unprofitable. Orbital motors for mobile off-road equipment are therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

26. Similarly, an increase in the price of hydraulic steering systems would not cause OEM customers to replace a hydraulic steering system in mobile off-road equipment with electric steering technology. Electric steering technology—the only alternative steering system that does not require a hydraulic steering unit—is largely unproven and more expensive than hydraulic steering technology. Electric steering, for example, is vulnerable in wet terrains and often lacks the power necessary to move cylinders connected to the wheels of large off-road equipment. Finally, the switching costs from hydraulic steering to electric steering are high and would require a costly redesign by OEMs.

27. Because of these factors, in the event of a small but significant increase in price by a hypothetical monopolist of steering units, substitution away from steering units would be insufficient to render the price increase unprofitable. Steering units for mobile off-road equipment are therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

B. Geographic Markets

28. OEMs located in the United States cannot reasonably turn to suppliers without a U.S. presence for the supply of orbital motors or steering units for mobile off-road equipment. Long lead times due to international shipping and unexpected delays in the delivery of products can cause significant business disruption. Customers similarly require that suppliers warehouse new and replacement parts to avoid costly delays or interruptions to business operations and expect local service and support from suppliers.

29. A hypothetical monopolist of orbital motors or steering units sold in the United States could profitably impose a small but significant non-transitory increase in price for orbital motors or steering units without losing sufficient sales to render the price increase unprofitable. Nor would the price increase be defeated by arbitrage, *e.g.,* by OEMs purchasing through subsidiaries located outside the United States. Accordingly, the relevant geographic market for the purposes of analyzing the effects of the acquisition on orbital motors and steering units for mobile off-road equipment under Section 7 of the Clayton Act, 15 U.S.C. 18, is the United States.

VI. Danfoss's Proposed Acquisition of Eaton's Hydraulics Business Is Likely To Result in Anticompetitive Effects

30. The proposed transaction would lessen competition and harm customers for orbital motors and steering units for mobile off-road equipment in the United States by eliminating the substantial head-to-head competition that currently exists between Danfoss and Eaton. Customers would pay higher prices and receive lower quality and service for orbital motors and steering units as a result of the acquisition.

31. In the United States, Danfoss and Eaton are the two largest suppliers of orbital motors for mobile off-road equipment, with market shares of approximately 53% and 24%, respectively. The only other major supplier of orbital motors for mobile off-road equipment has a 9% share of the market. Together, Danfoss and Eaton would account for over 75% of sales of orbital motors in United States.

32. In the United States, Danfoss and Eaton are the two largest suppliers of steering units for mobile off-road equipment, with market shares of approximately 43% and 41%, respectively. The only other major supplier of steering units for mobile off-road equipment has a considerably smaller market share of less than 1%. Together, Danfoss and Eaton would account for approximately 84% of sales of steering units in the United States.

33. As articulated in the Horizontal Merger Guidelines issued by the Department of Justice and the Federal Trade Commission (the ''Horizontal Merger Guidelines'' [1]), the Herfindahl-Hirschman Index (or ''HHI,'' as described in Appendix A) is a widely used measure of market concentration. Market concentration is often a useful way of measuring the likely anticompetitive effects of an acquisition. The more concentrated a market, the higher the likelihood that a transaction will result in a meaningful reduction in competition and harm customers. Markets in which the HHI exceeds 2,500 points are considered highly concentrated, and transactions that result in highly concentrated markets and increase the HHI by more than 200 points are presumed to be likely to enhance market power.

34. In the market for orbital motors for mobile off-road equipment, the pre-merger HHI is 3,605 and the post-merger HHI is 6,087, representing an increase in the HHI of 2,482. In the market for

[1] U.S. Department of Justice and the Federal Trade Commission, Horizontal Merger Guidelines, *available at https://www.justice.gov/atr/file/810276/download* (Aug. 19, 2010).

steering units for mobile off-road equipment, the pre-merger HHI is 4,155 and the post-merger HHI is 8,273, representing an increase in the HHI of 4,118. Under the Horizontal Merger Guidelines, the proposed acquisition will result in highly concentrated markets for both orbital motors and steering units for mobile off-road equipment and is thus presumed likely to enhance market power.

35. The HHI indicators of highly concentrated markets and enhanced market power are consistent with historical head-to-head competition between Danfoss and Eaton to supply orbital motors and steering units for mobile off-road equipment. Danfoss and Eaton compete directly on price, quality, product innovation, delivery, and technical service, and the competition between them has benefited U.S. customers of orbital motors and steering units for mobile off-road equipment. Danfoss and Eaton have a reputation for high-quality orbital motors and steering units, product developments that benefit OEMs, an extensive network of distributors throughout the United States, and localized customer support and service. As a result, Danfoss and Eaton are considered to be the two primary—and sometimes the only two—suppliers of orbital motors and steering units to customers in the United States.

36. For all of these reasons, the proposed transaction between Danfoss and Eaton likely would substantially lessen competition in the design, manufacture, and sale of orbital motors and steering units for mobile off-road equipment sold to customers in the United States and lead to higher prices, decreased quality of delivery and service, and diminished innovation.

VII. Absence of Countervailing Factors

37. Entry into the design, manufacture, and sale of orbital motors and steering units for mobile off-road equipment sold in United States is unlikely to be timely, likely, or sufficient to prevent the harm to competition caused by Danfoss's acquisition of Eaton's hydraulics business. A new entrant must have the technical capabilities necessary to design, manufacture, and sell orbital motors and steering units that meet customer requirements for quality, performance, and reliability. Additionally, a new entrant must have the requisite scale, an established reputation, and an extensive network of distributors to supply to all customers throughout the United States.

38. As a result of these entry barriers, entry into the market for the design, manufacture, and sale of orbital motors and steering units for mobile off-road equipment sold to customers in United States would not be timely, likely, or sufficient to defeat the substantial lessening of competition that likely would result from Danfoss's acquisition of Eaton's hydraulics business.

VIII. Violations Alleged

39. Danfoss's proposed acquisition of Eaton's hydraulics business likely would substantially lessen competition in the design, manufacture, and sale of orbital motors and steering units for mobile off-road equipment in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

40. Unless enjoined, the proposed acquisition would likely have the following anticompetitive effects, among others, related to the relevant market:

1. A substantial lessening of competition generally;

2. an elimination of actual and potential head-to-head competition between Danfoss and Eaton; and

3. a likely increase in prices and decrease in quality and innovation.

IX. Request for Relief

41. The United States requests that this Court:

1. Adjudge and decree that Danfoss's acquisition of Eaton's hydraulics business would be unlawful and violate Section 7 of the Clayton Act, 15 U.S.C. 18;

2. preliminarily and permanently enjoin and restrain Defendants and all persons acting on their behalf from consummating the proposed acquisition of Eaton's hydraulics business by Danfoss, or from entering into or carrying out any other contract, agreement, plan, or understanding which would combine Eaton's hydraulics business with Danfoss;

3. award the United States its costs for this action; and

4. award the United States such other and further relief as the Court deems just and proper.

Dated: July 14, 2021

Respectfully submitted,

Counsel for Plaintiff United States:

Richard Powers,
Acting Assistant Attorney General, Antitrust Division

Kathleen S. O'Neill,
Senior Director of Investigation and Litigation, Antitrust Division

Jay D. Owen,
Acting Chief,
Defense, Industrials, and Aerospace Section, Antitrust Division

SoYoung Choe,
Acting Assistant Chief, Defense, Industrials, and Aerospace Section, Antitrust Division

Rebecca Valentine * (D.C. Bar #989607)
Bashiri Wilson (D.C. Bar # 998075)
Trial Attorneys

Defense, Industrials, and Aerospace Section, Antitrust Division, 450 Fifth Street NW, Suite 8700, Washington, DC 20530, Telephone: (202) 476–0432, Facsimile: (202) 514–9033, Email: *rebecca.valentine@usdoj.gov.*
* Lead Attorney To Be Noticed

Appendix A

Definition of the Herfindahl–Hirschman Index

''HHI'' means the Herfindahl-Hirschman Index, a commonly accepted measure of market concentration. It is calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers. For example, for a market consisting of four firms with shares of 30 percent, 30 percent, 20 percent, and 20 percent, the HHI is 2,600 (302 + 302 + 202 + 202 = 2,600). The HHI takes into account the relative size distribution of the firms in a market and approaches zero when a market consists of a large number of small firms. The HHI increases both as the number of firms in the market decreases and as the disparity in size between those firms increases. Markets in which the HHI is above 2,500 are considered to be highly concentrated. *See* Horizontal Merger Guidelines § 5.3. Transactions that increase the HHI by more than 200 points in highly concentrated markets are presumed to be likely to enhance market power under the guidelines issued by the U.S. Department of Justice and Federal Trade Commission. *See id.*

United States District Court for the District of Columbia

United States of America, *Plaintiff,* v. Danfoss A/S, and Eaton Corporation PLC, *Defendants.*

Case No: 1:21–cv–1880–CJN

[Proposed] Final Judgment

Whereas, Plaintiff, United States of America, filed its Complaint on July 14, 2021,

And Whereas, the United States and Defendants, Danfoss A/S (''Danfoss'') and Eaton Corporation plc (''Eaton''), have consented to entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party relating to any issue of fact or law;

And Whereas, Defendants agree to make a divestiture to remedy the loss of competition alleged in the Complaint;

And Whereas, Defendants represent that the divestiture and other relief required by this Final Judgment can and will be made and that Defendants will

not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

Now therefore, it is *ordered*, *adjudged*, and *decreed*:

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Danfoss'' means Defendant Danfoss A/S, a Danish corporation with its headquarters in Nordborg, Denmark, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

B. ''Eaton'' means Defendant Eaton Corporation plc, an Irish corporation with its headquarters in Dublin, Ireland, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Interpump'' means Interpump Group S.p.A., an Italian corporation with its headquarters in Sant'llario d'Enza, Reggio Emilia, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

D. ''Acquirer'' means Interpump Group S.p.A. or another entity approved by the United States in its sole discretion to which Defendants divest the Divestiture Assets.

E. ''Danfoss Orbital Motor Business'' means Danfoss's global business of designing, manufacturing, and selling its OMP X, OMR X, OMEW, OMH, OMS, OMM, OML, CE, RE, RC, RS, DH, DS, DT, DR, D9, HB, HK, and WS models of orbital motor products.

F. ''Danfoss Hydraulic Steering Unit Business'' means Danfoss's global business of designing, manufacturing, and selling its OSPM, OSPP, LAGB, LAGU, LAGS, LAGC, LAGL, and LAGZ models of hydraulic steering unit products.

G. ''Danfoss Hydraulic Steering Unit IP Licenses'' means worldwide, non-exclusive, royalty-free, perpetual, paid-up, irrevocable licenses to the intellectual property listed in Exhibit 1.

H. ''Eaton Orbital Motor Assets'' means all of Eaton's assets used to manufacture its HP 30, VIS 30, VIS 40, and VIS 45 models of orbital motor products.

I. ''Eaton Hydraulic Steering Unit Assets'' means all of Eaton's assets used to manufacture its Series 10 and Series 20 models of hydraulic steering unit products.

J. ''Eaton Orbital Motor IP Licenses'' means worldwide, non-exclusive, royalty-free, perpetual, paid-up, irrevocable licenses to the intellectual property listed in Exhibit 2.

K. ''Eaton Hydraulic Steering Unit IP Licenses'' means worldwide, non-exclusive, royalty-free, perpetual, paid-up, irrevocable licenses to the intellectual property listed in Exhibit 3.

L. ''Char Lynn IP License'' means a non-exclusive, irrevocable, fully paid-up, royalty-free, perpetual license to use the ''Char Lynn'' trademark to market models HP 30, VIS 30, VIS 40, and VIS 45, or their equivalents, of orbital motors.

M. ''Divestiture Assets'' means the Danfoss Divestiture Assets and the Eaton Divestiture Assets.

N. ''Divestiture Date'' means the date on which the Divestiture Assets are divested to the Acquirer pursuant to this Final Judgment.

O. ''Danfoss Divestiture Assets'' means (i) all assets, located in Zhenjiang, China as of January 21, 2020, including lapping machines, grinders, testers, measurement devices, and any other assets that the United States, in its sole discretion, deems to be necessary for the manufacture of Danfoss's S70 model hydraulic steering unit product and (ii) all of Defendants' rights, titles, and interests in and to the Danfoss Orbital Motor Business, the Danfoss Hydraulic Steering Unit Business, and all other property and assets, tangible and intangible, wherever located, relating to or used in connection with the Danfoss Orbital Motor Business or Danfoss Hydraulic Steering Unit Business, including:

1. The facility located at 110 Bill Bryan Blvd., Hopkinsville, KY 42240 (the ''Hopkinsville Facility'');

2. the facility located at ul. Logistyezna 1, 55–040 Kobierzyce, Wroclaw (Poland) (the ''Wroclaw Facility'');

3. the facility located at Ludwigsluster Chaussee 5, 19370, Parchim (Germany) (the ''Parchim Facility'');

4. all other real property, including fee simple interests, real property leasehold interests and renewal rights thereto, improvements to real property, and options to purchase any adjoining or other property, together with all buildings, facilities, and other structures;

6. all tangible personal property, including fixed assets, machinery and manufacturing equipment, tools, vehicles, inventory, materials, office equipment and furniture, computer hardware, and supplies;

7. all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including supply agreements, teaming agreements, and leases, and all outstanding offers or solicitations to enter into a similar arrangement;

8. all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations issued or granted by any governmental organization, and all pending applications or renewals;

9. all records and data, including (a) customer lists, accounts, sales, and credits records, (b) production, repair, maintenance, and performance records, (c) manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees, (d) records and research data concerning historic and current research and development activities, including designs of experiments and the results of successful and unsuccessful designs and experiments, and (e) drawings, blueprints, and designs;

10. the Danfoss Hydraulic Steering Unit IP Licenses;

11. all intellectual property owned, licensed, or sublicensed, either as licensor or licensee, including (a) patents, patent applications, and inventions and discoveries that may be patentable, (b) registered and unregistered copyrights and copyright applications, and (c) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications; and

12. all other intangible property, including (a) commercial names and d/b/a names, (b) technical information, (c) computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, specifications for parts, specifications for devices, safety procedures (*e.g.,* for the handling of materials and substances), quality assurance and control procedures, and design tools, and (d) rights in internet websites and internet domain names.

Provided, however, that the Danfoss Divestiture Assets do not include (i) rights, titles, or interests in real property or tangible personal property located in Zhenjiang, China that is used to manufacture CE, RE, RC, and WS model orbital motor products that, at the Divestiture Date, are sold exclusively to

customers outside of the United States; (ii) rights, titles, or interests in real property or tangible personal property located in Nordborg, Denmark that is used to manufacture OMEWF model orbital motor products that, at the Divestiture Date, are sold exclusively to customers outside of the United States; or (iii) intellectual property listed in Exhibit 1.

P. ''Eaton Divestiture Assets'' means all of Defendants' rights, titles, and interests in and to the Eaton Orbital Motor Assets, the Eaton Hydraulic Steering Unit Assets, and all other property and assets, tangible and intangible, wherever located, relating to or used in connection with the Eaton Orbital Motor Assets or the Eaton Hydraulic Steering Unit Assets, including:

1. The Char Lynn IP License;

2. the Eaton Orbital Motor IP Licenses;

3. the Eaton Hydraulic Steering Unit IP Licenses;

4. the Eaton Divested Equipment and all other tangible personal property, including fixed assets, machinery and manufacturing equipment, tools, vehicles, inventory, materials, office equipment and furniture, computer hardware, and supplies;

5. all contracts, contractual rights, and customer relationships, and all other agreements, commitments, and understandings, including supply agreements, teaming agreements, and leases, and all outstanding offers or solicitations to enter into a similar arrangement;

6. all licenses, permits, certifications, approvals, consents, registrations, waivers, and authorizations issued or granted by any governmental organization, and all pending applications or renewals;

7. all records and data, including (a) customer lists, accounts, sales, and credits records, (b) production, repair, maintenance, and performance records, (c) manuals and technical information Defendants provide to their own employees, customers, suppliers, agents, or licensees, (d) records and research data concerning historic and current research and development activities, including designs of experiments and the results of successful and unsuccessful designs and experiments, and (e) drawings, blueprints, and designs;

8. all intellectual property owned, licensed, or sublicensed, either as licensor or licensee, including (a) patents, patent applications, and inventions and discoveries that may be patentable, (b) registered and unregistered copyrights and copyright applications, and (c) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications; and

9. all other intangible property, including (a) commercial names and d/b/a names, (b) technical information, (c) computer software and related documentation, know-how, trade secrets, design protocols, specifications for materials, specifications for parts, specifications for devices, safety procedures (*e.g.,* for the handling of materials and substances), quality assurance and control procedures, and design tools, and (d) rights in internet websites and internet domain names.

Provided, however, that the Eaton Divestiture Assets do not include: (i) Real property, (ii) tangible property, including fixed assets, machinery, and manufacturing equipment, used to manufacture Eaton's Series 20 model of hydraulic steering unit products; (iii) the Char Lynn trademark; (iv) intellectual property listed in Exhibit 2; (v) intellectual property listed in Exhibit 3; (vi) paint line assets used for the Eaton Orbital Motor Assets or Eaton Hydraulic Steering Unit Assets; or (vii) at the option of Acquirer, heat treat ovens, phosphate lines, or 80 ton broach used for the Eaton Orbital Motor Assets; or the HMS line used for the Eaton Hydraulic Steering Unit Assets.

Q. ''Eaton Divested Equipment'' means machining, assembly, and test assets relating to or used in connection with the production lines used for the Eaton Orbital Motor Assets or Eaton Hydraulic Steering Unit Assets. *Provided, however,* that the Eaton Divested Equipment does not include paint line assets used for the Eaton Orbital Motor Assets or Eaton Hydraulic Steering Unit Assets.

R. ''Including'' means including, but not limited to.

S. ''Relevant Personnel'' means all full-time, part-time, or contract employees of Danfoss wherever located, that the United States, in its sole discretion, deems to be primarily involved in the design, manufacture, or sale of Danfoss's OMP X, OMR X, OMEW, OMH, OMS, OMM, OML, CE, RE, RC, RS, DH, DS, DT, DR, D9, HB, HK, and WS models of orbital motor products and Danfoss's S70, OSPM, OSPP, LAGB, LAGU, LAGS, LAGC, LAGL, and LAGZ models of hydraulic steering unit products, at any time between January 21, 2020, and the Divestiture Date.

Provided, however, Relevant Personnel does not include employees of Danfoss that the United States, in its sole discretion, deems to be primarily engaged in human resources, legal, or other general or administrative support functions. The United States, in its sole discretion, will resolve any disagreement relating to which employees are Relevant Personnel.

T. ''Regulatory Approvals'' means any approvals or clearances pursuant to filings under antitrust, competition, or other U.S. or international laws that are required for Acquirer's acquisition of the Divestiture Assets to proceed.

U. ''Transaction'' means the proposed acquisition by Danfoss of certain assets and equity interests from Eaton, pursuant to the Stock and Asset Purchase Agreement between Eaton Corporation PLC as the Seller and Danfoss A/S as the Buyer, dated January 21, 2020.

III. Applicability

A. This Final Judgment applies to Danfoss and Eaton, as defined above, and all other persons in active concert or participation with any Defendant who receive actual notice of this Final Judgment.

B. If, prior to complying with Section IV and Section V of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of business units that include the Divestiture Assets, Defendants must require any purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from Acquirer.

IV. Divestitures

A. Defendant Danfoss is ordered and directed, within sixty (60) calendar days after the Court's entry of the Asset Preservation Stipulation and Order in this matter, to divest the Divestiture Assets in a manner consistent with this Final Judgment to Interpump or another Acquirer acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed sixty (60) calendar days in total and will notify the Court of any extensions.

B. If Defendant Danfoss has not received all Regulatory Approvals within sixty (60) calendar days after the Court's entry of the Asset Preservation Stipulation and Order in this matter, and Acquirer or Defendant Danfoss has initiated contact with any governmental entity to seek any Regulatory Approval within five (5) calendar days after the Court's entry of the Asset Preservation Stipulation and Order in this matter, the time period provided in Paragraph IV.A will be extended until ten (10) calendar days after that Regulatory Approval is received. This extension allowed for securing Regulatory Approvals may be

no longer than thirty (30) calendar days past the time period provided in Paragraph IV.A, unless the United States, in its sole discretion, consents to an additional extension.

C. Defendants must use best efforts to divest the Divestiture Assets as expeditiously as possible. Defendants must take no action that would jeopardize the completion of the divestiture ordered by the Court, including any action to impede the permitting, operation, or divestiture of the Divestiture Assets.

D. Unless the United States otherwise consents in writing, divestiture pursuant to this Final Judgment must include the entire Divestiture Assets and must be accomplished in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets can and will be used by Acquirer as part of a viable, ongoing business of designing, manufacturing, and selling orbital motors and hydraulic steering units for mobile off-road equipment and that the divestiture to Acquirer will remedy the competitive harm alleged in the Complaint.

E. The divestiture must be made to an Acquirer that, in the United States' sole judgment, has the intent and capability, including the necessary managerial, operational, technical, and financial capability, to compete effectively in the design, manufacture and sale of orbital motors and hydraulic steering units for mobile off-road equipment.

F. The divestiture must be accomplished in a manner that satisfies the United States, in its sole discretion, that none of the terms of any agreement between Acquirer and Defendant Danfoss gives Defendants the ability unreasonably to raise Acquirer's costs, to lower Acquirer's efficiency, or otherwise interfere in the ability of Acquirer to compete effectively in the design, manufacture, and sale of orbital motors and hydraulic steering units for mobile off-road equipment.

G. In the event Defendant Danfoss is attempting to divest the Divestiture Assets to an Acquirer other than Interpump, Defendant Danfoss promptly must make known, by usual and customary means, the availability of the Divestiture Assets. Defendant Danfoss must inform any person making an inquiry relating to a possible purchase of the Divestiture Assets that the Divestiture Assets are being divested in accordance with this Final Judgment and must provide that person with a copy of this Final Judgment. Defendants must offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets that are customarily provided in a due diligence process; *provided, however,* that Defendants need not provide information or documents subject to the attorney-client privilege or work-product doctrine. Defendants must make all information and documents available to the United States at the same time that the information and documents are made available to any other person.

H. Defendants must provide prospective Acquirers with (1) access to make inspections of the Divestiture Assets; (2) access to all environmental, zoning, and other permitting documents and information relating to the Divestiture Assets; and (3) access to all financial, operational, or other documents and information relating to the Divestiture Assets that would customarily be provided as part of a due diligence process. Defendants also must disclose all encumbrances on any part of the Divestiture Assets, including on intangible property.

I. Defendants must cooperate with and assist Acquirer in identifying and, at the option of Acquirer, in hiring all Relevant Personnel, including:

1. Within ten (10) business days following the filing of the Complaint in this matter, Defendant Danfoss must identify all Relevant Personnel to Acquirer and the United States, including by providing organization charts covering all Relevant Personnel.

2. Within ten (10) business days following receipt of a request by Acquirer, the United States, or the monitoring trustee, Defendant Danfoss must provide to Acquirer, the United States, and the monitoring trustee additional information relating to Relevant Personnel, including name, job title, reporting relationships, past experience, responsibilities, training and educational histories, relevant certifications, and job performance evaluations. Defendant Danfoss must also provide to Acquirer, the United States, and the monitoring trustee information relating to the current and accrued compensation and benefits of Relevant Personnel, including most recent bonuses paid, aggregate annual compensation, current target or guaranteed bonus, if any, any retention agreement or incentives, and any other payments due, compensation or benefit accrued, or promises made to the Relevant Personnel. If Defendant Danfoss is barred by any applicable law from providing any of this information, Defendant Danfoss must provide, within ten (10) business days following receipt of the request, the requested information to the full extent permitted by law and also must provide a written explanation of Defendant Danfoss's inability to provide the remaining information, including specifically identifying the provisions of the applicable laws.

3. At the request of Acquirer, Defendants must promptly make Relevant Personnel available for private interviews with Acquirer during normal business hours at a mutually agreeable location.

4. Defendants must not interfere with any effort by Acquirer to employ any Relevant Personnel. Interference includes offering to increase the compensation or improve the benefits of Relevant Personnel unless (a) the offer is part of a company-wide increase in compensation or improvement in benefits that was announced prior to January 21, 2020 or (b) the offer is approved by the United States in its sole discretion. Defendants' obligations under this Paragraph will expire six (6) months after the Divestiture Date.

5. For Relevant Personnel who elect employment with Acquirer within one hundred-eighty (180) calendar days of the Divestiture Date, Defendant Danfoss must waive all non-compete and non-disclosure agreements; vest and pay to the Relevant Personnel (or to Acquirer for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits or other compensation fully or partially accrued at the time of the transfer of the employee to Acquirer; vest any unvested pension and other equity rights; and provide all other benefits that those Relevant Personnel otherwise would have been provided had the Relevant Personnel continued employment with Defendants, including any retention bonuses or payments. Defendants may maintain reasonable restrictions on disclosure by Relevant Personnel of Defendants' proprietary non-public information that is unrelated to the design, manufacture, and sale of orbital motors and hydraulic steering units and not otherwise required to be disclosed by this Final Judgment.

J. Defendant Danfoss must warrant to Acquirer that (1) the Divestiture Assets will be operational and without material defect on the date of their transfer to Acquirer; (2) there are no material defects in the environmental, zoning, or other permits relating to the operation of the Divestiture Assets; and (3) Defendant Danfoss has disclosed all encumbrances on any part of the Divestiture Assets, including on intangible property. Following the sale of the Divestiture Assets, Defendants must not undertake, directly or indirectly, challenges to the environmental, zoning, or other permits

relating to the operation of the Divestiture Assets.

K. Defendants must assign, subcontract, or otherwise transfer all contracts, agreements, and customer relationships (or portions of such contracts, agreements, and customer relationships) included in the Divestiture Assets, including all supply and sales contracts, to Acquirer; *provided, however,* that for any contract or agreement that requires the consent of another party to assign, subcontract, or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or transfer. Defendants must not interfere with any negotiations between Acquirer and a contracting party.

L. Defendants must use best efforts to assist Acquirer to obtain all necessary licenses, registrations, and permits to operate the Divestiture Assets. Until Acquirer obtains the necessary licenses, registrations, and permits, Defendants must provide Acquirer with the benefit of Defendants' licenses, registrations, and permits to the full extent permissible by law.

M. Within twelve (12) months after the Court's entry of the Asset Preservation Stipulation and Order in this matter, Defendants must relocate the Eaton Divested Equipment to one or more locations as specified by Acquirer. In order to fulfill this obligation, the Eaton Divested Equipment must be fully operational at the new location(s). The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed six (6) months in total.

N. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendant Danfoss must enter into a supply contract or contracts for heat treatment services for the Danfoss Divestiture Assets located in Wroclaw, Poland; gerotors for Eaton's S10 model of hydraulic steering units; spools, sleeves, and gear sets for Danfoss's OSPP model of hydraulic steering units; shafts for Danfoss's OMS model of orbital motors; and the components for Eaton's HP30 2-speed model 22 orbital motor product listed in Exhibit 4, sufficient to meet Acquirer's needs, as determined by Acquirer, for a period of up to twelve (12) months, on terms and conditions reasonably related to market conditions for the supply of heat treatment services, gerotors, spools, sleeves, gear sets, shafts, and the components listed in Exhibit 4. Any amendment to or modification of any provision of any such supply contract is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of any supply contract for a total of up to an additional six (6) months. If Acquirer seeks an extension of the term of any supply contract, Defendants must notify the United States in writing at least sixty (60) days prior to the date the supply contract expires. Acquirer may terminate a supply contract, or any portion of a supply contract, without cost or penalty at any time upon commercially reasonable notice.

O. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendants must enter into a supply contract for HP 30, VIS 30, VIS 40, and VIS 45 models of orbital motor products and S10 and S20 models of hydraulic steering unit products sufficient to meet Acquirer's needs, as determined by Acquirer, for a period of up to eighteen (18) months, on terms and conditions reasonably related to market conditions for the supply of HP/VIS orbital motors and S10 and S20 Hydraulic Steering Units. Any amendment to or modification of any provision of any such supply contract is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of any supply contract for a total of up to an additional six (6) months. If Acquirer seeks an extension of the term of any supply contract, Defendants must notify the United States in writing at least sixty (60) days prior to the date the supply contract expires. Acquirer may terminate a supply contract, or any portion of a supply contract, without cost or penalty at any time upon commercially reasonable notice.

P. At the option of Acquirer, and subject to approval by the United States in its sole discretion, on or before the Divestiture Date, Defendant Danfoss must enter into a contract to provide transition services for back office, accounting, human resources, information technology services and support, and employee health and safety for the Divestiture Assets, and technical training services and support for the Eaton Divestiture Assets for a period of up to twelve (12) months on terms and conditions reasonably related to market conditions for the provision of the transition services. Any amendment to or modification of any provision of a contract to provide transition services is subject to approval by the United States, in its sole discretion. The United States, in its sole discretion, may approve one or more extensions of any contract for transition services for a total of up to an additional six (6) months. If Acquirer seeks an extension of the term of any contract for transition services, Defendants must notify the United States in writing at least three (3) months prior to the date the contract expires. Acquirer may terminate a contract for transition services, or any portion of a contract for transition services, without cost or penalty at any time upon commercially reasonable written notice. The employee(s) of Defendants tasked with providing transition services must not share any competitively sensitive information of Acquirer with any other employee of Defendants.

Q. For a period of one (1) year following the Divestiture Date, Defendants must not initiate customer-specific communications to solicit any customer for the portion of that customer's business covered by a contract, agreement, or relationship (or portion thereof) that is included in the Divestiture Assets; *provided, however,* that: (1) Defendants may respond to inquiries initiated by customers and enter into negotiations at the request of such customers (including responding to requests for quotation or proposal) to supply any business, whether or not such business was included in the Divestiture Assets; and (2) Defendants must maintain a log of telephonic, electronic, in-person, and other communications that constitute inquiries or requests from customers within the meaning of this Paragraph and make it available to the United States for inspection upon request. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed six (6) months in total.

R. If any term of an agreement between Defendants and Acquirer, including an agreement to effectuate the divestiture required by this Final Judgment, varies from a term of this Final Judgment, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

V. Appointment of Divestiture Trustee

A. If Defendants have not divested the Divestiture Assets within the period specified in Paragraph IV.A, Defendants must immediately notify the United States of that fact in writing. Upon application of the United States, which Defendants may not oppose, the Court will appoint a divestiture trustee selected by the United States and approved by the Court to effect the divestiture of the Divestiture Assets.

B. After the appointment of a divestiture trustee by the Court, only the divestiture trustee will have the right to

sell the Divestiture Assets. The divestiture trustee will have the power and authority to accomplish the divestiture to an Acquirer acceptable to the United States, in its sole discretion, at a price and on terms obtainable through reasonable effort by the divestiture trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and will have other powers as the Court deems appropriate. The divestiture trustee must sell the Divestiture Assets as quickly as possible.

C. Defendants may not object to a sale by the divestiture trustee on any ground other than malfeasance by the divestiture trustee. Objections by Defendants must be conveyed in writing to the United States and the divestiture trustee within ten (10) calendar days after the divestiture trustee has provided the notice of proposed divestiture required by Section VI.

D. The divestiture trustee will serve at the cost and expense of Defendant Danfoss pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion.

E. The divestiture trustee may hire at the cost and expense of Defendant Danfoss any agents or consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the divestiture trustee's judgment to assist with the divestiture trustee's duties. These agents or consultants will be accountable solely to the divestiture trustee and will serve on terms and conditions, including confidentiality requirements and conflict-of-interest certifications, approved by the United States in its sole discretion.

F. The compensation of the divestiture trustee and agents or consultants hired by the divestiture trustee must be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement that provides the divestiture trustee with incentives based on the price and terms of the divestiture and the speed with which it is accomplished. If the divestiture trustee and Defendant Danfoss are unable to reach agreement on the divestiture trustee's compensation or other terms and conditions of engagement within fourteen (14) calendar days of the appointment of the divestiture trustee by the Court, the United States, in its sole discretion, may take appropriate action, including by making a recommendation to the Court. Within three (3) business days of hiring an agent or consultant, the divestiture trustee must provide written notice of the hiring and rate of compensation to Defendant Danfoss and the United States.

G. The divestiture trustee must account for all monies derived from the sale of the Divestiture Assets sold by the divestiture trustee and all costs and expenses so incurred. Within thirty (30) calendar days of the Divestiture Date, the divestiture trustee must submit that accounting to the Court for approval. After approval by the Court of the divestiture trustee's accounting, including fees for unpaid services and those of agents or consultants hired by the divestiture trustee, all remaining money must be paid to Defendant Danfoss and the trust will then be terminated.

H. Defendants must use best efforts to assist the divestiture trustee to accomplish the required divestiture. Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, Defendants must provide the divestiture trustee and agents or consultants retained by the divestiture trustee with full and complete access to all personnel, books, records, and facilities of the Divestiture Assets. Defendants also must provide or develop financial and other information relevant to the Divestiture Assets that the divestiture trustee may reasonably request. Defendants must not take any action to interfere with or to impede the divestiture trustee's accomplishment of the divestiture.

I. The divestiture trustee must maintain complete records of all efforts made to sell the Divestiture Assets, including by filing monthly reports with the United States setting forth the divestiture trustee's efforts to accomplish the divestiture ordered by this Final Judgment. The reports must include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring any interest in the Divestiture Assets and must describe in detail each contact.

J. If the divestiture trustee has not accomplished the divestiture ordered by this Final Judgment within six (6) months of appointment, the divestiture trustee must promptly provide the United States with a report setting forth (1) the divestiture trustee's efforts to accomplish the required divestiture; (2) the reasons, in the divestiture trustee's judgment, why the required divestiture has not been accomplished; and (3) the divestiture trustee's recommendations for completing the divestiture. Following receipt of that report, the United States may make additional recommendations to the Court. The Court thereafter may enter such orders as it deems appropriate to carry out the purpose of this Final Judgment, which may include extending the trust and the term of the divestiture trustee's appointment by a period requested by the United States.

K. The divestiture trustee will serve until divestiture of all Divestiture Assets is completed or for a term otherwise ordered by the Court.

L. If the United States determines that the divestiture trustee is not acting diligently or in a reasonably cost-effective manner, the United States may recommend that the Court appoint a substitute divestiture trustee.

VI. Notice of Proposed Divestiture

A. Within two (2) business days following execution of a definitive agreement with an Acquirer other than Interpump to divest the Divestiture Assets, Defendants or the divestiture trustee, whichever is then responsible for effecting the divestiture, must notify the United States of the proposed divestiture. If the divestiture trustee is responsible for completing the divestiture, the divestiture trustee also must notify Defendants. The notice must set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets.

B. Within fifteen (15) calendar days of receipt by the United States of the notice required by Paragraph VI.A, the United States may request from Defendants, the proposed Acquirer, other third parties, or the divestiture trustee additional information concerning the proposed divestiture, the proposed Acquirer, and other prospective Acquirers. Defendants and the divestiture trustee must furnish the additional information requested within fifteen (15) calendar days of the receipt of the request, unless the United States provides written agreement to a different period.

C. Within forty-five (45) calendar days after receipt of the notice required by Paragraph VI.A or within twenty (20) calendar days after the United States has been provided the additional information requested pursuant to Paragraph VI.B, whichever is later, the United States will provide written notice to Defendants and any divestiture

trustee that states whether the United States, in its sole discretion, objects to the proposed Acquirer or any other aspect of the proposed divestiture. Without written notice that the United States does not object, a divestiture may not be consummated. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under Paragraph V.C of this Final Judgment. Upon objection by Defendants pursuant to Paragraph V.C, a divestiture by the divestiture trustee may not be consummated unless approved by the Court.

D. No information or documents obtained pursuant to this Section may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand-jury proceedings, for the purpose of evaluating a proposed Acquirer or securing compliance with this Final Judgment, or as otherwise required by law.

E. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the United States Department of Justice's Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Persons submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten (10) years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

F. If at the time that a person furnishes information or documents to the United States pursuant to this Section, that person represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give that person ten (10) calendar days' notice before divulging the material in any legal proceeding (other than a grand-jury proceeding).

VII. Financing

Defendants may not finance all or any part of Acquirer's purchase of all or part of the Divestiture Assets.

VIII. Asset Preservation

Defendants must take all steps necessary to comply with the Asset Preservation Stipulation and Order entered by the Court.

IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestiture required by this Final Judgment has been completed, each Defendant must deliver to the United States an affidavit, signed by each Defendant's Chief Financial Officer and General Counsel, describing in reasonable detail the fact and manner of that Defendant's compliance with this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits. Defendant Eaton's obligations under this Paragraph IX.A shall cease thirty (30) calendar days after the closing of the Transaction.

B. Each affidavit required by Paragraph IX.A must include: (1) The name, address, and telephone number of each person who, during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, an interest in the Divestiture Assets, and describe in detail each contact with such persons during that period; (2) a description of the efforts Defendants have taken to solicit buyers for and complete the sale of the Divestiture Assets and to provide required information to prospective Acquirers; and (3) a description of any limitations placed by Defendants on information provided to prospective Acquirers. Objection by the United States to information provided by Defendants to prospective Acquirers must be made within fourteen (14) calendar days of receipt of the affidavit, except that the United States may object at any time if the information set forth in the affidavit is not true or complete.

C. Defendants must keep all records of any efforts made to divest the Divestiture Assets until one (1) year after the Divestiture Date.

D. Within twenty (20) calendar days of the filing of the Complaint in this matter, each Defendant must deliver to the United States an affidavit signed by that Defendant's Chief Financial Officer and General Counsel that describes in reasonable detail all actions that Defendant has taken and all steps that Defendant has implemented on an ongoing basis to comply with Section VIII of this Final Judgment. The United States, in its sole discretion, may approve different signatories for the affidavits.

E. If a Defendant makes any changes to the actions and steps described in affidavits provided pursuant to Paragraph IX.D, the Defendant must, within fifteen (15) calendar days after any change is implemented, deliver to the United States an affidavit describing those changes.

F. Defendants must keep all records of any efforts made to comply with Section VIII until one (1) year after the Divestiture Date.

X. Appointment of Monitoring Trustee

A. Upon application of the United States, which Defendants may not oppose, the Court will appoint a monitoring trustee selected by the United States and approved by the Court.

B. The monitoring trustee will have the power and authority to monitor Defendants' compliance with the terms of this Final Judgment and the Asset Preservation Stipulation and Order entered by the Court and will have other powers as the Court deems appropriate. The monitoring trustee will have no responsibility or obligation for operation of the Divestiture Assets.

C. Defendants may not object to actions taken by the monitoring trustee in fulfillment of the monitoring trustee's responsibilities under any Order of the Court on any ground other than malfeasance by the monitoring trustee. Objections by Defendants must be conveyed in writing to the United States and the monitoring trustee within ten (10) calendar days of the monitoring trustee's action that gives rise to Defendants' objection.

D. The monitoring trustee will serve at the cost and expense of Defendant Danfoss pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion.

E. The monitoring trustee may hire, at the cost and expense of Defendant Danfoss, any agents and consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the monitoring trustee's judgment to assist with the monitoring trustee's duties. These agents or consultants will be solely accountable to the monitoring trustee and will serve on terms and conditions, including confidentiality requirements

and conflict-of-interest certifications, approved by the United States in its sole discretion.

F. The compensation of the monitoring trustee and agents or consultants retained by the monitoring trustee must be on reasonable and customary terms commensurate with the individuals' experience and responsibilities. If the monitoring trustee and Defendant Danfoss are unable to reach agreement on the monitoring trustee's compensation or other terms and conditions of engagement within fourteen (14) calendar days of the appointment of the monitoring trustee, the United States, in its sole discretion, may take appropriate action, including by making a recommendation to the Court. Within three (3) business days of hiring any agents or consultants, the monitoring trustee must provide written notice of the hiring and the rate of compensation to Defendant Danfoss and the United States.

G. The monitoring trustee must account for all costs and expenses incurred.

H. Defendants must use best efforts to assist the monitoring trustee to monitor Defendants' compliance with their obligations under this Final Judgment and the Asset Preservation Stipulation and Order. Subject to reasonable protection for trade secrets, other confidential research, development, or commercial information, or any applicable privileges, Defendants must provide the monitoring trustee and any agents or consultants retained by the monitoring trustee with full and complete access to all personnel, books, records, and facilities of the Divestiture Assets. Defendants may not take any action to interfere with or to impede accomplishment of the monitoring trustee's responsibilities.

I. The monitoring trustee must investigate and report on Defendants' compliance with this Final Judgment and the Asset Preservation Stipulation and Order, including compliance with all supply and transition service agreements and progress of production line transfers. The monitoring trustee must provide periodic reports to the United States setting forth Defendants' efforts to comply with their obligations under this Final Judgment and under the Asset Preservation Stipulation and Order. The United States, in its sole discretion, will set the frequency of the monitoring trustee's reports.

J. The monitoring trustee will serve until the divestiture of all the Divestiture Assets is finalized pursuant to either Section IV or Section V of this Final Judgment, Defendants have complied with the terms of the transition services agreements and supply contracts provided for in Paragraphs IV.N, IV.O, and IV.P of this Final Judgment, and Defendants have fulfilled all their obligations under Paragraphs IV.M and IV.Q of this Final Judgment, unless the United States, in its sole discretion, determines a different period is appropriate.

K. If the United States determines that the monitoring trustee is not acting diligently or in a reasonably cost-effective manner, the United States may recommend that the Court appoint a substitute.

XI. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or of related orders such as the Asset Preservation Stipulation and Order or of determining whether this Final Judgment should be modified or vacated, upon written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, and reasonable notice to Defendants, Defendants must permit, from time to time and subject to legally recognized privileges, authorized representatives, including agents retained by the United States:

1. To have access during Defendants' office hours to inspect and copy, or at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, relating to any matters contained in this Final Judgment. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, Defendants must submit written reports or respond to written interrogatories, under oath if requested, relating to any matters contained in this Final Judgment.

C. No information or documents obtained by the United States pursuant to this Section may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand jury proceedings, for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendants submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten (10) years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

E. If at the time that Defendants furnish information or documents to the United States pursuant to this Section, Defendants represent and identify in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give Defendants ten (10) calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

XII. Firewall

A. For a period of two (2) years following the filing of this Proposed Final Judgment, Defendants must implement and maintain procedures to prevent any employees of Defendants from sharing competitively sensitive information relating to the Divestiture Assets with personnel of Defendants with responsibilities relating to Danfoss's or Eaton's design, manufacture, and sale of hydraulic orbital motors or hydraulic steering units.

B. Defendants, within thirty (30) calendar days of the Court's entry of the Asset Preservation Stipulation and Order, must submit to the United States a document setting forth in detail the procedures implemented to effect compliance with this Section. Upon receipt of the document, the United States will inform Defendants within ten (10) business days whether, in its sole discretion, the United States approves or rejects Defendants' compliance plan. Within ten (10) business days of receiving a notice of rejection, Defendants must submit a revised compliance plan. The United

States may request that the Court determine whether Defendants' proposed compliance plan fulfills the requirements of Paragraph XII.A.

XIII. Limitations on Reacquisitions

Defendants may not reacquire any part of or any interest in the Divestiture Assets during the term of this Final Judgment without prior authorization of the United States.

XIV. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XV. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in a civil contempt action, a motion to show cause, or a similar action brought by the United States relating to an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

B. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition the United States alleges was harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In an enforcement proceeding in which the Court finds that Defendants have violated this Final Judgment, the United States may apply to the Court for an extension of this Final Judgment, together with other relief that may be appropriate. In connection with a successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that effort to enforce this Final Judgment, including in the investigation of the potential violation.

D. For a period of four (4) years following the expiration of this Final Judgment, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four (4) years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure the Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section.

XVI. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire ten (10) years from the date of its entry, except that after five (5) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and continuation of this Final Judgment is no longer necessary or in the public interest.

XVII. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this Final Judgment and the Competitive Impact Statement, public comments thereon, and any response to comments by the United States. Based upon the record before the Court, which includes the Competitive Impact Statement and, if applicable, any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16

_____

United States District Judge

EXHIBIT 1—DANFOSS HYDRAULIC STEERING UNIT LICENSES GRANTED TO ACQUIRER

Patent No.	Title	Country	Grant date
EP 1 910 151	Electrohydraulic Steering System with Cut-Off Valve and Sensor	Denmark	6-Oct-10.
EP 1 910 151	Electrohydraulic Steering System with Cut-Off Valve and Sensor	France	6-Oct-10.
EP 1 910 151	Electrohydraulic Steering System with Cut-Off Valve and Sensor	Germany	6-Oct-10.
EP 1 910 151	Electrohydraulic Steering System with Cut-Off Valve and Sensor	Great Britain	6-Oct-10.
EP 1 910 151	Electrohydraulic Steering System with Cut-Off Valve and Sensor	Italy	6-Oct-10.
CN 101233040	Electrohydraulic Steering System with Cut-Off Valve and Sensor	China	12-Oct-11.
US 7,677,351	Electrohydraulic Steering System with Cut-Off Valve and Sensor	USA	16-Mar-10.
3410349	Plug	European Design	7-Oct-16.
304354829	Plug	China	14-Nov-17.

EXHIBIT 2—EATON ORBITAL MOTOR LICENSES GRANTED TO ACQUIRER

Patent No.	Title	Country	Grant date
201380038257.X	COMBINED MOTOR AND BRAKE ROTATING BRAKE–RELEASE PISTON.	China	28-Dec-16.
2895739	COMBINED MOTOR AND BRAKE ROTATING BRAKE–RELEASE PISTON.	European Patent Convention.	
6214652	COMBINED MOTOR AND BRAKE ROTATING BRAKE–RELEASE PISTON.	Japan	29-Sep-17.
9175563	COMBINED MOTOR AND BRAKE WITH ROTATING BRAKE–RELEASE PISTON.	United States	3-Nov-15.

EXHIBIT 2—EATON ORBITAL MOTOR LICENSES GRANTED TO ACQUIRER—Continued

Patent No.	Title	Country	Grant date
EP2875237	FREEWHEEL HYDRAULIC MOTOR	European Patent Convention.	28-Mar-18.
602013035067.1	FREEWHEEL HYDRAULIC MOTOR	Germany	28-Mar-18.
EP2875237	FREEWHEEL HYDRAULIC MOTOR	Great Britain	28-Mar-18.
502018000016462	FREEWHEEL HYDRAULIC MOTOR	Italy	28-Mar-18.
9551222	FREEWHEEL HYDRAULIC MOTOR	United States	24-Jan-17.

EXHIBIT 3—EATON HYDRAULIC STEERING UNIT LICENSES TO ACQUIRER

Patent No.	Title	Country	Grant date
6769249	LOW SLIP STEERING SYSTEM AND IMPROVED FLUID CONTROLLER THEREFOR.	United States	3-Aug-03.
6769451	POWER BEYOND STEERING UNIT WITH BYPASS	United States	3-Aug-03.
6782698	STEERING CONTROL UNIT WITH LOW NULL BAND LOAD SENSING BOOST.	United States	31-Aug-03.
EP2250068	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	Denmark	10-Jul-13.
EP2250068	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	France	10-Jul-13.
602009017015.5	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	Germany	10-Jul-13.
EP2250068	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	Great Britain	10-Jul-13.
EP2250068	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	Italy	10-Jul-13.
EP2250068	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	Spain	10-Jul-13.
8225603	FLUID CONTROLLER WITH MULTIPLE FLUID METERS	United States	24-Jul-12.
3010785B1	FLUID CONTROLLER WITH LOAD SENSE AND FLOW AMPLIFICATION.	European Patent Convention.	17-Jun-14.
9920776	FLUID CONTROLLER WITH LOAD SENSE AND FLOW AMPLIFICATION.	United States	20-Mar-18.
4725695	FLUID CONTROLLER AND FLUID METER BYPASS ARRANGEMENT.	Japan	22-Apr-11.
529996	FLUID CONTROLLER AND FLUID METER BYPASS ARRANGEMENT.	South Korea	14-Nov-11.

EXHIBIT 4—ORBITAL MOTOR COMPONENTS FOR EATON'S HP30 2-SPEED MODEL 22 ORBITAL MOTOR PRODUCT

Component part No.	Part description
8483–000	Shaft.
8731–000	Front Retainer.
6037923–001	Bearing Housing.
202879–004	Drive Spacer.
5992182–008	Drive.
5992182–010	Drive.
9004–002	Quad Ring.
8732–000	Backup Washer.
6212–000	Dust Seal.
6037922–001	Adapter Plate.
6181–000	Bearing Spacer.
9001–002	Thrust Bearing Washer.
9001–003	Thrust Bearing Washer.
9001–004	Thrust Washer.
9002–003	Thrust Bearing.
9002–004	Thrust Bearing.
9003–002	Radial Bearing.
16292–100	Cap Screw.
15045–000	Seal.
25001–046	O Ring.

United States District Court for the District of Columbia

United States of America, *Plaintiff,* v. Danfoss A/S, and Eaton Corporation PLC, *Defendants.*

Civil Action No.: 1:21–cv–1880–CJN

Competitive Impact Statement

In accordance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (the ''APPA'' or ''Tunney Act''), the United States of America files this Competitive Impact Statement relating to the proposed Final Judgment filed in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On January 21, 2020, Defendant Danfoss A/S (''Danfoss'') entered into a binding agreement with Defendant Eaton Corporation (''Eaton'') to acquire Eaton's hydraulics business for approximately $3.3 billion in cash. The United States filed a civil antitrust Complaint on July 14, 2021 seeking to enjoin the proposed transaction. The Complaint alleges that the likely effect of this transaction would be to substantially lessen competition in the design, manufacture, and sale of orbital motors and hydraulic steering units in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

At the same time the Complaint was filed, the United States filed a proposed Final Judgment and an Asset Preservation Stipulation and Order (''Stipulation and Order''), which are designed to remedy the loss of competition alleged in the Complaint.

Under the proposed Final Judgment, which is explained more fully below, Defendant Danfoss is required to divest the following assets: The Danfoss Orbital Motor Business; the Danfoss Steering Unit Business; the Eaton Orbital Motor Assets; the Eaton Steering Unit Assets, and certain Intellectual Property (collectively ''The Divestiture Assets''). Under the terms of the Stipulation and Order, Defendants must take certain steps to ensure that the Divestiture Assets that must be divested are operated as ongoing, economically viable, competitive Divestiture Assets for the design, manufacture, and sale of orbital motors and steering units and must take all other actions to preserve and maintain the full economic viability, marketability, and competitiveness of the Divestiture Assets to be divested.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof.

II. Description of Events Giving Rise to the Alleged Violation

(A) The Defendants and the Proposed Transaction

Danfoss and Eaton are global corporations based in Nordborg, Denmark and Dublin, Ireland, respectively, that manufacture components of hydraulic power systems for industrial and agricultural use. Defendants' hydraulic components make it possible to steer, propel, and operate equipment used to pave roads, harvest produce, construct buildings, and perform other heavy industrial and agricultural tasks across the United States every day. Pursuant to a Transaction Agreement dated January 21, 2020, Danfoss intends to acquire Eaton's hydraulics business for approximately $3.3 billion.

(B) The Competitive Effects of the Transaction

The Complaint alleges that the transaction as proposed will lead to anticompetitive effects in the markets for the design, manufacture, and sale of hydraulic orbital motors (''orbital motors'') and hydraulic steering units (''steering units'').

a. Relevant Product Markets

The Complaint alleges that orbital motors for mobile off-road equipment and steering units for mobile off-road equipment are lines of commerce, or relevant product markets, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18. Orbital motors, also called ''low-speed, high-torque'' motors, are a low-cost way to move heavy loads in a slow, and thus controlled, way. Steering units direct hydraulic fluid in response to commands from equipment operators and are necessary for any hydraulic steering system to function.

In the event of a small but significant increase in price by a hypothetical monopolist of orbital motors, the Complaint alleges that substitution away from orbital motors would be insufficient to render the price increase unprofitable. Other technologies, such as vane, gear, piston, or electric motors, do not offer the same level of performance, are less efficient, or cost more than an orbital motor. Therefore, these technologies are not reasonable substitutes for orbital motors. Orbital motors for mobile off-road equipment are therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

Similarly, in the event of a small but significant increase in price by a hypothetical monopolist of steering units, the Complaint alleges that substitution away from steering units would be insufficient to render the price increase unprofitable. Electric steering technology—the only alternative steering system that does not require a hydraulic steering unit—is largely unproven and more expensive than hydraulic steering technology. The switching costs from hydraulic steering to electric steering are high and would require a costly redesign by Original Equipment Manufacturers (''OEMs''). Steering units for mobile off-road equipment are therefore a line of commerce, or relevant product market, for purposes of analyzing the effects of the acquisition under Section 7 of the Clayton Act, 15 U.S.C. 18.

b. Relevant Geographic Markets

The Complaint alleges that OEMs located in the United States wish to avoid business disruption and cannot reasonably turn to suppliers without a U.S. presence for the supply of orbital motors or steering units for mobile off-road equipment. Long lead times due to international shipping and unexpected delays in the delivery of products can cause significant business disruption. Customers similarly require that suppliers warehouse new and replacement parts to avoid costly delays or interruptions to business operations and expect local service and support from suppliers. Thus, a hypothetical monopolist of orbital motors or steering units sold in the United States could profitably impose a small but significant non-transitory increase in price for orbital motors or steering units without losing sufficient sales to render the price increase unprofitable. Nor would the price increase be defeated by arbitrage, *e.g.,* by OEMs purchasing through subsidiaries located outside the United States. Accordingly, the relevant geographic market for purposes of analyzing the effects of the acquisition on orbital motors and steering units for mobile off-road equipment under Section 7 of the Clayton Act, 15 U.S.C. 18, is the United States.

c. Anticompetitive Effects of the Proposed Transaction

The Complaint alleges that the transaction as proposed would lessen competition and harm customers for orbital motors and steering units for mobile off-road equipment in the United States. The Herfindahl-Hirschman Index (''HHI''), as articulated in the Horizontal Merger Guidelines issued by the Department of Justice and the Federal Trade Commission, measures the likely anticompetitive effects of an acquisition by assessing how concentrated a market is. The more concentrated a market, the higher the likelihood that a transaction will result in a meaningful reduction in competition and harm customers. HHI calculations in the markets for both orbital motors and steering units indicate that the proposed acquisition will result in highly concentrated markets and is thus presumed likely to enhance market power.

The HHI indicators of highly concentrated markets and enhanced market power are consistent with historical head-to-head competition between Danfoss and Eaton to supply orbital motors and steering units for mobile off-road equipment. Danfoss and Eaton compete directly on price, quality, product innovation, delivery, and technical service, and the competition between them has benefited U.S. customers of orbital motors and steering units for mobile off-road equipment. Danfoss and Eaton have a reputation for high-quality orbital motors and steering units, product developments that benefit OEMs, an extensive network of distributors throughout the United States, and localized customer support and service. As a result, Danfoss and Eaton are considered to be the two primary—and sometimes the only two—suppliers of orbital motors and steering units to customers in the United States.

d. Difficulty of Entry

The Complaint alleges that entry of additional competition into the design, manufacture, and sale of orbital motors and steering units sold in North America is unlikely to be timely, likely, or sufficient to prevent the harm to competition caused by Danfoss's acquisition of Eaton's hydraulics business. A new entrant must have the technical capabilities necessary to design, manufacture, and sell orbital motors and steering units that meet customer requirements for quality, performance, and reliability. Additionally, a new entrant must have the requisite scale, an established reputation, and an extensive network of distributors to supply to all customers throughout the United States.

III. Explanation of the Proposed Final Judgment

The relief required by the proposed Final Judgment will remedy the loss of competition alleged in the Complaint by establishing an independent and economically viable competitor in the market for the design, manufacture, and sale of orbital motors and steering units.

Paragraph IV.A of the proposed Final Judgment requires Defendant Danfoss, within 60 days after the entry of the Stipulation and Order by the Court, to divest the Divestiture Assets to Interpump Group S.p.A. (''Interpump'') or an alternative acquirer acceptable to the United States, in its sole discretion. If the 60 days expire while Defendants are waiting for regulatory approval from U.S. or international regulators, Paragraph IV.B extends the time allowed for the divestiture to take place to ten calendar days after the Regulatory Approval has been received. The extension may be no longer than 30 calendar days, unless the United States, in its sole discretion, consents to an additional extension.

(A) Divestiture Assets

The Divestiture Assets consist of the Danfoss Divestiture Assets and the Eaton Divestiture Assets. Taken together, the Divestiture Assets will form a viable, ongoing business that can compete effectively in the hands of an acquirer approved by the United States, in its sole discretion. The combination of product model lines from both Defendants ensures that an acquirer will have the breadth and scale necessary to succeed while preserving Danfoss's headquarters in Nordborg, Denmark, which houses businesses that are not being divested.

(B) Danfoss Divestiture Assets

The Danfoss Divestiture Assets are defined in Paragraph II.O as all tangible and intangible assets relating to or used in connection with the Danfoss Orbital Motor Business or the Danfoss Hydraulic Steering Unit Business—including three facilities that are located in Hopkinsville, Kentucky; Wroclaw, Poland; and Parchim, Germany. The Danfoss Orbital Motor Business and Danfoss Hydraulic Steering Unit Business, in turn, are defined by model of orbital motor or steering unit in Paragraphs II.E and II.F and comprise Danfoss's business of designing, manufacturing, and selling these orbital motors and steering units in the United States. The Danfoss Divestiture Assets also include assets necessary for the acquirer to manufacture Danfoss' S70 model of steering unit, which currently is in development. Certain assets located in Zhenjiang, China and Nordborg, Denmark are excluded from the Danfoss Divestiture Assets because they are not used for the orbital motors and hydraulic units at issue for sale to U.S. customers.

(C) Eaton Divestiture Assets

The Eaton Divestiture Assets are defined in Paragraph II.P as all tangible and intangible assets relating to or used in connection with the Eaton Orbital Motor Assets or the Eaton Hydraulic Steering Unit Assets. The Eaton Orbital Motor Assets and Eaton Hydraulic Steering Unit Asset, in turn, are defined by model of orbital motor or steering unit in Paragraphs II.H and II.I and comprise all the assets used to manufacture these models of orbital motors and steering units. Unlike the Danfoss Divestiture Assets, the Eaton Divestiture Assets do not include real property. Instead, the Eaton Orbital Motor Assets and Eaton Hydraulic Steering Unit Assets will move to the divested facility located in Hopkinsville, KY. The Eaton Divestiture Assets will include all fixed assets, machinery, and manufacturing equipment for the Eaton Orbital Motor Assets and Eaton Hydraulic Steering Unit Assets except Eaton's Series 20 model of hydraulic steering unit products. The Eaton Divestiture Assets also do not include the transfer of paint line assets (*see* Paragraph II.Q), which are instead included in the Danfoss Divestiture Assets.

(D) Intellectual Property

With the exceptions of the intellectual property listed in Exhibits 1, 2, or 3, and the Char Lynn license, all Intellectual Property including, but not limited to (a) patents, patent applications, and inventions and discoveries that may be patentable, (b) registered and unregistered copyrights and copyright applications, and (c) registered and unregistered trademarks, trade dress, service marks, trade names, and trademark applications will be divested to the acquirer.

The intellectual property listed in Exhibits 1, 2, and 3 is necessary for the Divestiture Assets as well as for assets that will be retained by Defendant Danfoss. Consequently, the acquirer will receive worldwide, non-exclusive, royalty-free, perpetual, paid-up, irrevocable licenses to the intellectual property listed in Exhibits 1, 2, and 3. Likewise, the acquirer will receive a worldwide, non-exclusive, royalty-free, perpetual, paid-up, irrevocable license to use the Char Lynn name, which is used for certain Eaton orbital motor models. This license will allow the acquirer to transition these products to its own product names.

(E) Divestiture Provisions

Section IV of the proposed Final Judgment contains additional detail about how the divestitures should be carried out. Defendants are required to act expeditiously (Paragraph IV.C), to divest the Divestiture Assets in such a way as to satisfy the United States, in its sole discretion, that the Divestiture Assets will be used as a part of a viable ongoing business and will remedy the competitive harm alleged in the Complaint (Paragraph IV.D). The divestiture must be made to an acquirer that, in the United States' sole judgment, has the intent and capability to compete effectively in the design, manufacture and sale of orbital motors and hydraulic steering units for mobile off-road equipment (Paragraph IV.E) and must be done in such a manner that Defendants cannot interfere in the acquirer's efforts to compete effectively in the design, manufacture, and sale of orbital motors and hydraulic steering units for mobile off-road equipment. If the Divestiture Assets are divested to an acquirer other than Interpump, Paragraphs IV.G and IV.H require Defendants to make certain information available to the prospective acquirer, including a copy of the proposed Final Judgment.

Paragraph IV.I of the proposed Final Judgment contains provisions intended to facilitate the acquirer's efforts to hire certain employees. Specifically, Paragraph IV.I of the proposed Final Judgment requires Defendant Danfoss to provide the acquirer and the United States with organization charts and information relating to these employees and to make them available for interviews. It also provides that Defendants must not interfere with any efforts by the acquirer to hire these employees. In addition, for employees who elect employment with the acquirer, Defendant Danfoss must waive all non-compete and non-disclosure agreements, vest and pay to these employees (or to the acquirer for payment to the employee) on a prorated basis any bonuses, incentives, other salary, benefits or other compensation fully or partially accrued at the time of the transfer of the employee to the acquirer; vest any unvested pension or other equity rights; and provide all other benefits that the employees would generally be provided had those employees continued employment with Defendants, including but not limited to any retention bonuses or payments.

Paragraph IV.J of the proposed Final Judgment ensures that the Divestiture Assets are unencumbered and operable from the first day that the acquirer takes ownership. Paragraph IV.L ensures that the acquirer will receive all necessary licenses, registrations, and permits to

operate the Divestiture Assets once they are transferred.

Paragraph IV.K of the proposed Final Judgment will facilitate the transfer to the acquirer of customers and other contractual relationships that are included within the Divestiture Assets. Defendants must transfer all contracts, agreements, and relationships to the acquirer and must use best efforts to assign, subcontract, or otherwise transfer contracts or agreements that require the consent of another party before assignment, subcontracting, or other transfer.

Paragraph IV.M of the proposed Final Judgment requires Defendants to accomplish the move of Eaton Divested Equipment, as defined in Paragraph II.Q, to the acquirer's preferred location within 12 months after the Court's entry of the Stipulation and Order. In the interim, the supply contracts mandated by Paragraph IV.O will ensure that the acquirer can serve its new customer base without disruption. Paragraphs IV.M and IV.O allow the United States to extend the time to move the Eaton Divested Equipment and the terms of the supply contracts up to an additional six months if necessary.

Paragraphs IV.N and IV.O of the proposed Final Judgment address supply contracts between Defendant Danfoss and the acquirer. Paragraph IV.N requires Defendant Danfoss, at the acquirer's option, to enter into a supply contract for certain services and components, such as heat treatment services and gerotors, sufficient to meet the acquirer's needs, as determined by the acquirer, for a period of up to 12 months. The acquirer may terminate the supply contract, or any portion of it, without cost or penalty at any time upon commercially reasonable notice, and any amendments to or modifications of any provisions of a supply contract are subject to approval by the United States in its sole discretion. Paragraph IV.O requires Defendants to enter into a supply contract for certain models of orbital motor and steering unit products, for a period of up to 18 months. Upon the acquirer's request, the United States, in its sole discretion, may approve one or more extensions of the supply contracts contemplated in Paragraphs IV.N and IV.O for up to an additional six months. This provision will help to ensure that the acquirer will not face disruption to its supply of these input products during an important transitional period.

The proposed Final Judgment requires Defendant Danfoss to provide certain transition services to maintain the viability and competitiveness of the Divestiture Assets during the transition to the acquirer. Paragraph IV.P of the proposed Final Judgment requires Defendant Danfoss, at the acquirer's option, to enter into a transition services agreement for back office, accounting, human resources, information technology services and support, employee health and safety, and technical training services and support for a period of up to 12 months. The acquirer may terminate the transition services agreement, or any portion of it, without cost or penalty at any time upon commercially reasonable notice. The paragraph further provides that the United States, in its sole discretion, may approve one or more extensions of this transition services agreement for a total of up to an additional 6 months and that any amendments to or modifications of any provisions of a transition services agreement are subject to approval by the United States in its sole discretion. Paragraph IV.P also provides that employees of Defendants tasked with supporting this agreement must not share any competitively sensitive information of the acquirer with any other employee of Defendants, unless such sharing is for the sole purpose of providing transition services to the acquirer.

Paragraph IV.Q of the proposed Final Judgment requires Defendants to refrain for one year from soliciting customers for the portion of the customer's business that is transferring to the acquirer. Defendants may respond to inquiries initiated by such customers and enter into negotiations at the request of the customers but must maintain a log of any such inquiries and requests. This provision gives the acquirer time to establish a performance record with new customers without interference from Defendants. Paragraph IV.Q allows the United States to extend the time period of this provision up to an additional six months if necessary.

Paragraph IV.R ensures that the terms of the proposed Final Judgment supersede any terms of agreement between Defendants and the acquirer that are inconsistent with the proposed Final Judgment.

(F) Divestiture Trustee Provisions

If Defendants do not accomplish the divestiture within the period prescribed in Paragraph IV.A or IV.B of the proposed Final Judgment, Section V of the proposed Final Judgment provides that the Court will appoint a divestiture trustee selected by the United States to effect the divestiture. If a divestiture trustee is appointed, the proposed Final Judgment provides that Defendant Danfoss must pay all costs and expenses of the trustee. The divestiture trustee's compensation must be structured so as to provide an incentive for the trustee based on the price and terms obtained and the speed with which the divestiture is accomplished. After the divestiture trustee's appointment becomes effective, the trustee must provide monthly reports to the United States setting forth his or her efforts to accomplish the divestiture. If the divestiture has not been accomplished within six months of the divestiture trustee's appointment, the United States may make recommendations to the Court, which will enter such orders as appropriate, in order to carry out the purpose of the Final Judgment, including by extending the trust or the term of the divestiture trustee's appointment by a period requested by the United States.

(G) Monitoring Trustee Provisions

Section X of the proposed Final Judgment provides that the United States may appoint a monitoring trustee who will have the power and authority to investigate and report on Defendants' compliance with the terms of the Final Judgment and the Stipulation and Order, including compliance with all supply and transition service agreements and progress of production line transfers, and will have other powers as the Court deems appropriate. The monitoring trustee will not have any responsibility or obligation for the operation of Defendants' businesses. The monitoring trustee will serve at Defendant Danfoss' expense, on such terms and conditions as the United States approves, and Defendants must assist the monitoring trustee in fulfilling his or her obligations. The monitoring trustee will provide periodic reports to the United States and will serve until the divestiture of all the Divestiture Assets is finalized pursuant to either Section IV or Section V of this Final Judgment and Defendant Danfoss has complied with the terms of the transition services agreements and supply contracts provided for in this Final Judgment, unless the United States, in its sole discretion, determines a different period is appropriate.

(H) Firewall Provision

The relocation of the Eaton Divested Equipment to a location specified by acquirer will require Defendants' employees to train employees of the acquirer on how to properly operate the equipment. Section XII of the proposed Final Judgment requires Defendants to implement and maintain a firewall to prevent the exchange of competitively sensitive information between Defendants and the acquirer.

Specifically, Defendants must implement and maintain procedures to prevent any employees of Defendants from sharing competitively sensitive information relating to the Divestiture Assets with personnel of Defendants with responsibilities relating to Danfoss's or Eaton's design, manufacture, and sale of hydraulic orbital motors or hydraulic steering units. Such a firewall will prevent competitively sensitive information about the Divestiture Assets from being used to influence business decisions relating to Danfoss's or Eaton's design, manufacturing, or sale of orbital motors or steering units. The implementation of these procedures for a two-year period will ensure that the information cannot be used while it is still competitively sensitive. After two years, any information will be sufficiently out of date to no longer pose a risk and the firewall can be eliminated. Under Paragraph XII.B, Defendants must, within 30 days of entry of the Stipulation and Order, submit to the United States a document setting forth in detail the procedures each has implemented to effect compliance with Section XII. The United States will determine, in its sole discretion, whether to approve or reject Defendants' proposed compliance plans.

(I) Compliance and Enforcement Provisions

The proposed Final Judgment also contains provisions designed to promote compliance with and make enforcement of the Final Judgment as effective as possible. Paragraph XV.A provides that the United States retains and reserves all rights to enforce the Final Judgment, including the right to seek an order of contempt from the Court. Under the terms of this paragraph, Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance with the Final Judgment with the standard of proof that applies to the underlying offense that the Final Judgment addresses.

Paragraph XV.B provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment is intended to remedy the loss of competition the United States alleges would otherwise be harmed by the transaction. Defendants agree that they will abide by the proposed Final Judgment and that they may be held in contempt of the Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph XV.C provides that if the Court finds in an enforcement proceeding that a Defendant has violated the Final Judgment, the United States may apply to the Court for an extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with investigating and enforcing violations of the Final Judgment, Paragraph XV.C provides that, in any successful effort by the United States to enforce the Final Judgment against a Defendant, whether litigated or resolved before litigation, the Defendant must reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with any effort to enforce the Final Judgment, including the investigation of the potential violation.

Paragraph XV.D states that the United States may file an action against a Defendant for violating the Final Judgment for up to four years after the Final Judgment has expired or been terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision, therefore, makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

(J) Term of the Final Judgment

Finally, Section XVI of the proposed Final Judgment provides that the Final Judgment will expire 10 years from the date of its entry, except that after five years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and that continuation of the Final Judgment is no longer necessary or in the public interest.

IV. Remedies Available to Potential Private Plaintiffs

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website.

Written comments should be submitted in English to: Jay Owen, Acting Chief, Defense, Industrials, and Aerospace Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street NW, Suite 8700, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against Danfoss's acquisition of certain assets and equity interests of Eaton's hydraulics business. The United States is satisfied, however, that the relief required by the proposed Final Judgment will remedy the anticompetitive effects alleged in the Complaint, preserving competition for the design, manufacture, and sale of orbital motors and hydraulic steering units. Thus, the proposed Final Judgment achieves all or substantially all of the relief the United States would have obtained through litigation but avoids the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the APPA for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments or ''consent decrees'' in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

> (A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: The court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' (internal citations omitted)); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.''' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters

that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: July 14, 2021

Respectfully submitted,

For Plaintiff United States of America:

REBECCA VALENTINE* (D.C. Bar #989607),
Trial Attorney,
Defense, Industrials, and Aerospace Section, Antitrust Division, 450 Fifth Street NW, Suite 8700, Washington, DC 20530, Telephone: (202) 476–0432, Facsimile: (202) 514–9033, Email: *rebecca.valentine@usdoj.gov.*
*Lead Attorney To Be Noticed

[FR Doc. 2021–15728 Filed 7–22–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–861]

Importer of Controlled Substances Application: Arizona Department of Corrections

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Arizona Department of Corrections has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before August 23, 2021. Such persons may also file a written request for a hearing on the application on or before August 23, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 7, 2021, Arizona Department of Corrections, 1305 E Butte Avenue, ASPC-Florence, Florence, Arizona 85132–9221, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Pentobarbital	2270	II

The facility intends to import the above-listed controlled substance for legitimate use. This particular controlled substance is not available for the intended legitimate use within the current domestic supply of the United States. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–15710 Filed 7–22–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number 1121–0334]

Agency Information Collection Activities; Proposed Collection Comments Requested; Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired: 2021 Survey of Campus Law Enforcement Agencies (SCLEA)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, Volume 86, Number 94, page 26944 on Tuesday, May 18, 2021, allowing a 60-day comment period. Following publication of the 60-day notice, BJS did not receive any comments on the proposed information collection.

DATES: Comments are encouraged and will be accepted for 30 days until August 23, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should

address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this Information Collection

(1) *Type of Information Collection:* Reinstatement of the Survey of Campus Law Enforcement Agencies (SCLEA), with changes, a previously approved collection for which approval has expired.

(2) *The Title of the Form/Collection:* 2021 Survey of Campus Law Enforcement Agencies (SCLEA).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number for the questionnaire is CJ–42. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will be campus law enforcement agencies (LEAs) serving public and private 2- and 4-year postsecondary educational institutions with a full-time enrollment of 1,000 or more students. Periodically since 1995, BJS has collected information about the personnel, policies, and practices of campus law enforcement agencies via the Survey of Campus Law Enforcement Agencies (SCLEA). This survey has been used to produce nationally representative estimates on campus law enforcement personnel, duties, administration, technology, officer selection, officer training, equipment, and jurisdiction. The survey instrument was reviewed by practitioners and subject matter experts to update it from the 2011 form and ensure it covers current topics of interest to campus law enforcement while reducing respondent burden. BJS plans to publish the information collected in a report and archive the data for public use.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An agency-level survey will be sent to approximately 1,860 campus LEA respondents. The expected burden placed on these respondents is about 1 hour per respondent.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There is an estimated 1,860 total burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: July 20, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–15716 Filed 7–22–21; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

U.S. Marshals Service

[OMB Number 1105–0106]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Currently Approved Collection; Comments Requested: Form USM–164, Applicant Appraisal Questionnaire

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), U.S. Marshals Service (USMS), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until September 21, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any additional information, please contact Nicole Timmons either by mail at CG–3, 10th Floor, Washington, DC 20530–0001, by email at *Nicole.Timmons@usdoj.gov,* or by telephone at 202–236–2646.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
— Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
— Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
— Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection (check justification or form 83):* Extension without change of a currently approved collection.

2. *The Title of the Form/Collection:* Form USM–164, Applicant Appraisal Questionnaire.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): Form USM–164.

Component: U.S. Marshals Service, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals (supervisors, peers, subordinates).

Other (if applicable): [None].

Abstract: This form is used to collect applicant reference information. Reference checking is an objective evaluation of an applicant's past job performance based on information collected from key individuals (*e.g.,* supervisors, peers, subordinates) who have known and worked with the

applicant. Reference checking is a necessary supplement to the evaluation of resumes and other descriptions of training and experience, and allows the selecting official to hire applicants with a strong history of performance. The questions on this form have been developed following the OPM, MSPB, and DOJ ''Best Practice'' guidelines for reference checking.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 500 respondents will utilize the form, and it will take each respondent approximately 20 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 167 hours, which is equal to 500 (total # of annual responses) * 20 minutes.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: July 20, 2021.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2021–15718 Filed 7–22–21; 8:45 am]

BILLING CODE 4410–04–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, *Unemployment Insurance (UI) Title XII Advances and Voluntary Repayment Process.* This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by September 21, 2021.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Joe Williams by telephone at (202) 693–2928 (this is not a toll-free number), TTY 1–877–889–5617, (this is not toll-free number) or by email at *williams.joseph@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, Room S–4524, 200 Constitution Avenue NW, Washington, DC 20210; by email: *williams.joseph@dol.gov;* or by Fax (202) 693–3975.

FOR FURTHER INFORMATION CONTACT: Cynthia Greene by telephone at (202) 693–2724 (this is not a toll-free number) or by email at *Cynthia.greene.m@dol.gov.*

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

Title XII, Section 1201, of the Social Security Act (SSA) provides for advances to states from the Federal Unemployment Account (FUA). The law further sets out specific requirements to be met by a state requesting an advance:

- The Governor, or designee, must apply for the advance;
- The application must cover a three-month period and the Secretary of Labor (Secretary) must be furnished with estimates of the amounts needed in each month of the three month period;
- The application must be made on such forms and shall contain such information and data (fiscal and otherwise) concerning the operation and administration of the state unemployment compensation law as the Secretary deems necessary or relevant to the performance of his or her duties under this title;
- The amount required by any state for the payment of compensation in any month shall be determined with due allowance for contingencies and taking into account all other amounts that will be available in the state's unemployment fund for the payment of compensation in such month; and
- The term ''compensation'' means cash benefits payable to individuals with respect to their unemployment exclusive of expenses of administration.

Section 1202(a) of the SSA provides that the Governor of any state may at any time request that funds be transferred from the account of such state to the FUA in repayment of part or all of the balance of advances made to such state under Section 1201. These applications and repayments may be requested by an individual designated for that authority in writing by the Governor. Sections 1201 and 1202(a) of the SSA authorize this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB control number 1205–0199.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, (*e.g.,* permitting electronic submission of responses).

Agency: DOL–ETA.

Type of Review: Revision.

Title of Collection: Unemployment Insurance (UI) Title XII Advances and Voluntary Repayments Process.

Form: None.

OMB Control Number: 1205–0199.

Affected Public: State Workforce Agencies.

Estimated Number of Respondents: 19.

Frequency: Varies.

Total Estimated Annual Responses: 19.

Estimated Average Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 19.

Total Estimated Annual Other Cost Burden: $0.

(Authority: 44 U.S.C. 3506(c)(2)(A))

Suzan G. LeVine,

Principal Deputy Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2021–15657 Filed 7–22–21; 8:45 am]

BILLING CODE 4510–FW–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by August 23, 2021. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–7420, or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670) as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2022–003

1. *Applicant*: Dr. George Watters, Director, AMLR Program, Southwest Fisheries Science Center, National Marine Fisheries Service, 8901 La Jolla Shores Drive, La Jolla, CA 92037

Activity for Which Permit is Requested: Waste management permit. This permit application pertains to ship and shore-based research and logistic activities conducted by the National Oceanic and Atmospheric Administration's (NOAA) Antarctic Marine Living Resources (AMLR) Program. The AMLR Program conducts research from a vessel platform in the Antarctic Peninsula region, collecting environmental, oceanographic, primary productivity, finfish, and prey data. Research is also conducted at two temporary field camps in the South Shetland Islands, Antarctica: Cape Shirreff and Copacabana. The scope of the application pertains to environmental and waste management issues resulting from proposed research, logistic and construction activities by the U.S. AMLR program between 2021 and 2026.

Ocean-based research activities will include the deployment of retrievable instrumentation. Instruments to be deployed include several long-range underwater gliders to measure environmental conditions and population densities, as well as up to 20 stationary moorings. Unoccupied Aerial Systems (UAS) will also be deployed from research vessels for surveying and censusing purposes. Deployment of all retrievable instrumentation will be performed by trained personnel associated with the research project.

Activities proposed at the Cape Shirreff field camp include the necessary construction of new temporary camp structures and the removal of previous temporary structures. Care will be taken to minimize environmental disturbance throughout construction and resulting structures are planned to occupy an approximate footprint similar to that of existing structures. Continuation of long-term research activities at the Cape Shirreff field camp will include deployment and maintenance of up to 30 autonomous cameras to assist in studies of avian breeding colonies, deployment of snow gauges and continued use of UAS for census surveying of surrounding fauna. Research activities proposed at the Copacabana field camp are similar to those at Cape Shirreff, including deployment of autonomous cameras and use of UAS for surveying purposes. All UAS pilots are licensed FAA remote aircraft pilots and care will be taken to follow all best practices for UAS operation in polar regions along with all appropriate safety measures.

Wastes and designated pollutants associated with typical field camp operations will be generated, released, stored, and removed at both camps. The field camps will release wastes to air in the form of emissions resulting from the combustion of gasoline, propane, and charcoal. Releases of wastes to water will be limited to greywater and human sewage only. Wastes and designated pollutants resulting from scientific research include materials used to mark animals and attach necessary instrumentation. Additional waste may be generated by construction activities at Cape Shirreff, but mitigation measures will be put in place to minimize the introduction of waste into the environment. For designated pollutants stored at field camps, strict protocols for storage and handling will be followed. All U.S. AMLR personnel will receive proper training on handling and management of designated pollutants prior to deployment.

Location: Cape Shirreff, Livingston Island; Copacabana, western shore of Admiralty Bay; Western Antarctic Peninsula.

Dates of Permitted Activities: October 1, 2021–July 31, 2026.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–15677 Filed 7–22–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by August 23, 2021. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–7420, or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670) as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and the designation of certain animals and certain geographic areas a requiring special protection.

Application Details

Permit Application: 2022–001

1. *Applicant*: Luis Huckstadt, Institute of Marine Sciences, University of California Santa Cruz.

Activity for Which Permit is Requested: Take, Harmful interference, Import into U.S.A. The applicant proposes to study the foraging behavior, physiology, and habitat utilization of crabeater seals in the West Antarctic Peninsula. In each of three field seasons, the applicant would capture and tag no more than 40 adult individuals. Individual seals will be sedated and anesthetized during tagging and biological sampling procedures. Proposed procedures include the following: Weighing and measuring of individuals, flipper tagging and marking, attaching of instrumentation, tissue sampling, collecting blood samples and measuring blood volume, swabbing of mucous membranes, and determining body composition by metamorphic measurements.

Location: West Antarctic Peninsula.

Dates of Permitted Activities: January 1, 2022–December 31, 2024.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–15042 Filed 7–22–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information (RFI) on an Implementation Plan for a National Artificial Intelligence Research Resource

AGENCY: White House Office of Science and Technology Policy and National Science Foundation.

ACTION: Request for information.

SUMMARY: The Office of Science and Technology Policy and the National Science Foundation are issuing this Request for Information (RFI) to inform the work of the National Artificial Intelligence Research Resource (NAIRR) Task Force (''Task Force''). The Task Force has been directed by Congress to develop an implementation roadmap for a shared research infrastructure that would provide Artificial Intelligence (AI) researchers and students across scientific disciplines with access to computational resources, high-quality data, educational tools, and user support.

DATES: To be considered, responses and comments must be received, no later than 11:59 p.m., EDT on September 1, 2021.

ADDRESSES: Comments submitted in response to this notice may be sent by any of the following methods:

- *Email: NAIRR-responses@nitrd.gov.* Email submissions should be machine-readable and not be copy-protected. Submissions should include ''*RFI Response: National AI Research Resource*'' in the subject line of the message.
- *Mail:* Attn: Wendy Wigen, NCO, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA.

Instructions: Response to this RFI is voluntary. Each individual or institution is requested to submit only one response. Submissions must be in 12 point or larger font, include a page number on each page, and not exceed 10 pages. Responses should include the name of the person(s) or organization(s) filing the comment. Responses should refer to the particular topic number(s) and letter(s), as listed below, to which the comments pertain.

Responses to this RFI may be posted online at *www.ai.gov.* Therefore, responses must be appropriate for posting publicly without change or redaction, and we request that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT: Wendy Wigen and *NAIRR-responses@nitrd.gov,* (202) 459–9683. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

Congress directed the National Science Foundation (NSF), in coordination with the White House Office of Science and Technology Policy (OSTP), to establish the NAIRR Task Force in the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Public Law 116–283 § 5106, and in accordance with the provisions of the Federal Advisory Committee Act. The mandate of the Task Force is to investigate the feasibility and advisability of establishing and sustaining a NAIRR and propose a roadmap detailing how such a resource should be established and sustained.

The NAIRR is envisioned as a shared computing and data infrastructure that would provide AI researchers and students across scientific fields with access to a holistic advanced computing ecosystem. This would include secure, privacy-preserving frameworks; high-quality, representative datasets; and appropriate educational tools and user support mechanisms. The goal for such a national resource is to democratize access to the cyberinfrastructure that fuels AI research and development, enabling all of America's diverse AI researchers to fully participate in

exploring innovative ideas for advancing AI, including communities, institutions, and regions that have been traditionally underserved—especially with regard to AI research and related education opportunities.

Composed of members from government, academia, and the private sector, the NAIRR Task Force is required to submit an interim report to Congress and the President by May 2022, with a final report to be issued in November 2022. Find more information on the Task Force members and upcoming meetings at *AI.gov*.

As outlined in § 5106(b) of Public Law 116–283, the implementation roadmap developed by the Task Force should include the following:

A. Goals for establishment and sustainment of a National Artificial Intelligence Research Resource and metrics for success;

B. A plan for ownership and administration of the National Artificial Intelligence Research Resource, including:

i. An appropriate agency or organization responsible for the implementation, deployment and administration of the Research Resource; and

ii. A governance structure for the Research Resource, including oversight and decision-making authorities;

C. A model for governance and oversight to establish strategic direction, make programmatic decisions, and manage the allocation of resources;

D. Capabilities required to create and maintain a shared computing infrastructure to facilitate access to advanced computing resources for researchers across the country, including provision of curated data sets, compute resources, educational tools and services, a user-interface portal, secure access control, resident expertise, and scalability of such infrastructure;

E. An assessment of, and recommended solutions to, barriers to the dissemination and use of high-quality government data sets as part of the National Artificial Intelligence Research Resource;

F. An assessment of security requirements associated with the National Artificial Intelligence Research Resource and its management of access controls;

G. An assessment of privacy and civil rights and civil liberties requirements associated with the National Artificial Intelligence Research Resource and its research;

H. A plan for sustaining the National Artificial Intelligence Research Resource, including through Federal funding and partnerships with the private sector; and

I. Parameters for the establishment and sustainment of the National Artificial Intelligence Research Resource, including agency roles and responsibilities.

This RFI seeks input from a broad array of stakeholders on the topics set forth below. Comments from the public will be used to inform the Task Force's consideration of options and development of an implementation roadmap.

Responders are invited to provide answers to the following questions (please number your responses accordingly):

1. What options should the Task Force consider for any of roadmap elements A through I above, and why? [Please take care to annotate your responses to this question by indicating the letter(s) of the item (A through I in the list above) for which you are identifying options.]

2. Which capabilities and services (see, for example, item D above) provided through the NAIRR should be prioritized?

3. How can the NAIRR and its components reinforce principles of ethical and responsible research and development of AI, such as those concerning issues of racial and gender equity, fairness, bias, civil rights, transparency, and accountability?

4. What building blocks already exist for the NAIRR, in terms of government, academic, or private-sector activities, resources, and services?

5. What role should public-private partnerships play in the NAIRR? What exemplars could be used as a model?

6. Where do you see limitations in the ability of the NAIRR to democratize access to AI R&D? And how could these limitations be overcome?

Submitted by the National Science Foundation and the White House Office of Science and Technology Policy on July 19, 2021.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

Stacy Murphy,

Operations Manager, White House Office of Science and Technology Policy.

[FR Doc. 2021–15660 Filed 7–22–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by August 23, 2021. This application may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Polly Penhale, ACA Permit Officer, at the above address, 703–292–7420, or *ACApermits@nsf.gov*.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR 670) as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

Application Details

Permit Application: 2022–002

1. *Applicant*: Dr. George Watters, Director, AMLR Program, Southwest Fisheries Science Center, National Marine Fisheries Service, 8901 La Jolla Shores Drive, La Jolla, CA 92037

Activity for Which Permit is Requested: Take, Harmful Interference, Enter Antarctic Specially Protected Areas, Import into USA. This permit application pertains to research activities conducted by the National Oceanic and Atmospheric Administration's (NOAA) Antarctic Marine Living Resources (AMLR) Program. The U.S. AMLR Program proposes to take pinniped species in the Antarctic Peninsula region as part of a long-term ecosystem monitoring program established in 1986. Permission

is requested for take and harmful interference for Antarctic fur seals (*Arctocephalus gazelle*), leopard seals (*Hydrurga leptonyx*), Weddell seals (*Leptonychotes weddellii*), crabeater seals (*Lobodon carcinophaga*), southern elephant seals (*Mirounga leonine*) and Ross seals (*Ommatophoca rossii*) by harassment associated with life-history studies and surveys to census or estimate abundance and distribution of pinnipeds. Specific take activities include capture/handling/release of animals for studies of attendance behavior, diving, and at-sea foraging location, diet, and population dynamics. Animals will be sedated and anesthetized during tagging and sampling procedures. Procedures include standard measuring of morphometrics, ultra-sounding, attaching of instrumentation, blood and tissue sampling and flipper marking/tagging. All studies of foraging ecology, population dynamics, mark-recapture, census, reproductive success, and energetics are part of a long-term monitoring effort coordinated with other Antarctic treaty nations under the auspices of Convention for the Conservation of Antarctic Marine Living Resources.

The U.S. AMLR Program also proposes continue studies of the behavioral ecology and population biology of the Adélie, gentoo, chinstrap and king penguins, as well as interactions among these species and their principal avian predators. Specific take activities associated with avian research include capture/handling/release, attaching of instrumentation, tagging/banding, weighing/measuring of individuals, tissue and egg sampling, diet sampling, placing of nest markers and censusing. The number of takes per annum of each avian species will be as follows: Chinstrap penguin (*Pygoscelis antarcticus),* Adélie penguin (*Pygoscelis adeliae),* Gentoo penguin (*Pygoscelis papua),* king penguin (*Aptenodytes patagonicus),* brown skua(*Catharacta lonnbergi*), south polar skua (*Catharacta maccormicki),* giant petrel (*macronectes giganteus*), kelp gull (*Larus dominicanus),* blue-eyed shag (*Phalacrocorax atriceps),* snowy sheathbill (*Chionis alba*) and cape petrel (*Daption capensis).* Those protocols related to the CCAMLR Ecosystem Monitoring Program (CEMP) are described by CCAMLR

The U.S. AMLR Program requests permission to continue long-term studies at the Cape Shirreff and Copacabana research sites. Additionally, the Program anticipates conducting intermittent peninsula-wide pinniped and seabird surveys. As such, access to all ASPAs in the South Shetland Islands and in the Antarctic Peninsula region is requested. Entry to sites will be made via U.S. AMLR charter or NSF vessels, with immediate access via zodiac operations. Peninsula-wide pinniped and seabird surveys may include the use of unmanned aerial vehicles and photogrammetry. All species, pinniped and avian, are subject to harmful interference due to census (aerial or ground) and other work described in this application.

Location: Antarctic Peninsula region, South Shetland Islands vicinity: Cape Shirreff, Livingston Island; San Telmo Islands; Copacabana, western shore of Admiralty Bay; and Lions Rump, King George Island.

ASPA 108, Green Island, Berthelot Islands, Antarctic Peninsula
ASPA 112, Coppermine Peninsula, Robert Island
ASPA 113, Litchfield Island, Arthur Harbor, Palmer Archipelago
ASPA 125, Fildes Peninsula, King George Island, South Shetland Islands
ASPA 126, Byers Peninsula, Livingston Island, South Shetland Islands
ASPA 128, Western Shore of Admiralty Bay, King George Island
ASPA 132, Potter Peninsula, King George Island, South Shetland Islands
ASPA 133, Harmony Point, Nelson Island, South Shetland Island
ASPA 134, Cierva Point offshore islands, Danco Coast, Antarctic Peninsula
ASPA 139, Biscoe Point, Anvers Island
ASPA 140, Shores of Port Foster, Deception Island, South Shetland Islands
ASPA 144, Chile Bay
ASPA 145, Port Foster, Deception Island, South Shetland Islands
ASPA 146, South Bay, Doumer Island, Palmer Archipelago
ASPA 148, Mount Flora, Hope Bay, Antarctic Peninsula
ASPA 149, Cape Shirreff, Livingston Island, South Shetland Islands
ASPA 150, Ardley Island, Maxwell Bay, King George Island, South Shetland Islands
ASPA 151, Lions Rump, King George Island, South Shetland Islands
ASPA 152, Western Bransfield Strait, Antarctic Peninsula
ASPA 153, East Dallmann Bay, Antarctic Peninsula
ASPA 171, Narebski Point, Barton Peninsula, King George Island

Dates of Permitted Activities: October 1, 2021–July 31, 2026.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2021–15676 Filed 7–22–21; 8:45 am]

BILLING CODE 7555–01–P

OFFICE OF PERSONNEL MANAGEMENT

Submission for Review: Establishment Information Form, DD 1918, Wage Data Collection Form, DD 1919, Wage Data Collection Continuation Form, DD 1919C, 3206–0036

AGENCY: Office of Personnel Management.

ACTION: 30-Day Notice and request for comments.

SUMMARY: The Office of Personnel Management (OPM) offers the general public and other Federal agencies the opportunity to comment on an existing information collection request (ICR) 3206–0036, Establishment Information Form (DD 1918), Wage Data Collection Form (DD 1919), and Wage Data Collection Continuation Form (DD 1919C). As required by the Paperwork Reduction Act of 1995 as amended by the Clinger-Cohen Act, OPM is soliciting comments for this collection.

DATES: Comments are encouraged and will be accepted until August 23, 2021. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Office of Personnel Management, Employee Services, Pay and Leave, 1900 E Street NW, Room 7H31, Washington, DC 20415–8200, Attention: Brenda L. Roberts, Deputy Associate Director for Pay and Leave, by phone 202–606–7400, or sent via electronic mail to *pay-leave-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: The information collection was previously published in the **Federal Register** on February 26, 2021, at Volume 86 FR 11804 allowing for a 60-day public comment period. No comments were received for this information collection. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the

proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

The Establishment Information Form, the Wage Data Collection Form, and the Wage Data Collection Continuation Form are wage survey forms developed by OPM for use by the Department of Defense to establish prevailing wage rates for Federal Wage System employees.

Analysis

Agency: Employee Services, Office of Personnel Management.

Title: Establishment Information Form (DD 1918), Wage Data Collection Form (DD 1919), and Wage Data Collection Continuation Form (DD 1919C).

OMB Number: 3260–0036.

Frequency: Annually.

Affected Public: Private Sector Establishments.

Number of Respondents: 21,760.

Estimated Time per Respondent: 1.5 hours.

Total Burden Hours: 32,640.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2021–15638 Filed 7–22–21; 8:45 am]

BILLING CODE 6325–39–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–114 and CP2021–116]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 27, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–114 and CP2021–116; *Filing Title:* USPS Request to Add Priority Mail Contract 713 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 19, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* July 27, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–15703 Filed 7–22–21; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92439; File No. SR–NYSEArca–2021–54]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To List and Trade Shares of the Cambiar Large Cap ETF, Cambiar Small Cap ETF and Cambiar SMID ETF

July 19, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 9, 2021, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under Rule 8.900–E (Managed Portfolio Shares): Cambiar Large Cap ETF, Cambiar Small Cap ETF and Cambiar SMID ETF. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

NYSE Arca Rule 8.900–E permits the listing and trading, or trading pursuant to unlisted trading privileges (''UTP''), of Managed Portfolio Shares, which are securities issued by an actively managed open-end investment management company.[4] Rule 8.900–E(b)(1) requires the Exchange to file separate proposals under Section 19(b) of the Act before listing and trading any series of Managed Portfolio Shares on the Exchange. Therefore, the Exchange is submitting this proposal in order to list and trade Managed Portfolio Shares of the Cambiar Large Cap ETF, Cambiar Small Cap ETF and Cambiar SMID ETF (each a ''Fund'' and, collectively, the ''Funds'') under Rule 8.900–E.

The Commission has previously approved listing and trading on the Exchange of Managed Portfolio Shares under NYSE Arca Rule 8.900–E.[5]

Description of the Funds and the Trust

The shares of each Fund (the ''Shares'') will be issued by The Advisors' Inner Circle Fund (the ''Trust''), a statutory trust organized under the laws of the State of Massachusetts and registered with the Commission as an open-end management investment company.[6] The investment adviser to each Fund will be Cambiar Investors, LLC (the ''Adviser''). SEI Investments Distribution Company (the ''Distributor'') will serve as the distributor of each of the Funds' Shares. All statements and representations made in this filing regarding (a) the description of the portfolio or reference assets, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules shall constitute continued listing requirements for listing the Shares on the Exchange, as provided under Rule 8.900–E(b)(1).

Rule 8.900–E(b)(4) provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer, such investment adviser will erect and maintain a ''fire wall'' between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition of and/or changes to such Investment Company portfolio and/or the Creation Basket.[7] Any person related to the investment adviser or Investment Company who makes decisions pertaining to the Investment Company's portfolio composition or has access to information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket.

Rule 8.900–E(b)(4) is similar to Commentary .03(a)(i) and (iii) to Rule 5.2–E(j)(3); however, Commentary .03(a) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds.[8] Rule 8.900–E(b)(4) is also similar to Commentary .06 to Rule 8.600–E related to Managed Fund Shares, except that Rule 8.900–E(b)(4) relates to establishment and maintenance of a ''fire wall'' between the investment adviser and personnel of

[4] Rule 8.900–E(c)(1) provides that the term ''Managed Portfolio Share'' means a security that (a) represents an interest in an investment company registered under the Investment Company Act of 1940 (''Investment Company'') organized as an open-end management investment company that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in a Creation Unit, or multiples thereof, in return for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value and delivered to the Authorized Participant (as defined in the Investment Company's Form N–1A filed with the Commission) through a Confidential Account; (c) when aggregated into a Redemption Unit, or multiples thereof, may be redeemed for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value delivered to the Confidential Account for the benefit of the Authorized Participant; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.

[5] *See* Securities Exchange Act Release Nos. 89663 (August 25, 2020), 85 FR 53868 (August 31, 2020) (Sr–NYSEArca–2020–48) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of Gabelli ETFs Under Rule 8.900–E, Managed Portfolio Shares); 90528 (November 30, 2020), 85 FR 78389 (December 4, 2020) (SR–NYSEArca–2020–80) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of Alger Mid Cap 40 ETF and Alger 25 ETF Under Rule 8.900–E); and 90683 (December 16, 2020), 85 FR 83665 (December 22, 2020) (SR–NYSEArca–2020–94) (Order Approving a Proposed Rule Change, as Modified by Amendments No. 1 and No. 2, To List and Trade Shares of the AdvisorShares Q Portfolio Blended Allocation ETF and AdvisorShares Q Dynamic Growth ETF Under NYSE Arca Rule 8.900–E).

[6] The Trust is registered under the 1940 Act. On May 10, 2021, the Trust filed a registration statement on Form N–1A under the Securities Act of 1933 (the ''1933 Act'') and the 1940 Act for the Funds (File No. 811–06400) (''Registration Statement''). The Commission issued an order granting exemptive relief to the Trust (''Exemptive Order'') under the 1940 Act on May 11, 2021 (Investment Company Act Release No. 34268). The Exemptive Order was granted in response to the Trust's application for exemptive relief (the ''Exemptive Application'') (File No. 812–15191). The description of the operation of the Trust and the Funds herein is based, in part, on the Registration Statement.

[7] Rule 8.900–E(c)(5) provides that the term ''Creation Basket'' means, on any given business day, the names and quantities of the specified instruments (and/or an amount of cash) that are required for an AP Representative to deposit in-kind on behalf of an Authorized Participant in exchange for a Creation Unit and the names and quantities of the specified instruments (and/or an amount of cash) that will be transferred in-kind to an AP Representative on behalf of an Authorized Participant in exchange for a Redemption Unit, which will be identical and will be transmitted to each AP Representative before the commencement of trading.

[8] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser and its related personnel will be subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violations, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above. The Funds will also be required to comply with Exchange rules relating to disclosure, including Rule 5.3–E(i).

the broker-dealer or broker-dealer affiliate, as applicable, with respect to an Investment Company's portfolio and Creation Basket, and not just to the underlying portfolio, as is the case with Managed Fund Shares.

The Adviser is not registered as a broker-dealer and is not affiliated with any broker-dealer. In the event (a) the Adviser or any sub-adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer, or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to personnel of the broker-dealer or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and/or Creation Basket. Any person related to the Adviser or the Trust who makes decisions pertaining to a Fund's portfolio composition or that has access to information regarding a Fund's portfolio composition or that has access to information regarding a Fund's portfolio or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio or changes thereto and the Creation Basket.

Further, Rule 8.900–E(b)(5) requires that any person or entity, including an AP Representative (as defined below), custodian, Reporting Authority, distributor, or administrator, who has access to non-public information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket, must be subject to procedures reasonably designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket.

Description of the Funds [9]

Each Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application and Exemptive Order and the holdings will be consistent with all requirements in the Exemptive Application and Exemptive Order.[10]

Cambiar Large Cap ETF

The Fund's investment objective is to seek total return and capital preservation. Under normal circumstances, the Fund will invest at least 80% of its net assets in common stocks of large-cap companies. The Fund generally considers large-cap companies to be companies with a market capitalization in excess of $10 billion at time of purchase.

Cambiar Small Cap ETF

The Fund's investment objective is to seek long-term capital appreciation. Under normal circumstances, the Fund will invest at least 80% of its net assets in common stocks of small-cap companies. The Fund generally considers small-cap companies to be companies with market capitalizations not greater than either that of the largest company in the Russell 2000® Value Index or $3.5 billion, whichever is greater at the time of initial purchase.

Cambiar SMID ETF

The Fund's investment objective is to seek long-term capital appreciation. Under normal circumstances, the Fund will invest at least 80% of its net assets in common stocks of small- to mid-sized companies. The Fund generally considers small- and mid-sized companies to be companies with market capitalizations not greater than either that of the largest company in the Russell 2500® Value Index or $12 billion, whichever is greater at the time of initial purchase.

Investment Restrictions

Each Fund's holdings will be consistent with all requirements described in the Exemptive Application and Exemptive Order.[11]

Each Fund's investments, including derivatives, will be consistent with its investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, for each Fund, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2X or −3X) of the Fund's benchmark.

Creations and Redemptions of Shares

Creations and redemptions of Shares will take place as described in Rule 8.900–E. Specifically, in connection with the creation and redemption of Creation Units [12] and Redemption Units,[13] the delivery or receipt of any portfolio securities in-kind will be required to be effected through a separate confidential brokerage account (a ''Confidential Account'').[14] Authorized Participants (''AP''), as defined in the applicable Form N–1A filed with the Commission, will sign an agreement with an AP Representative [15] establishing the Confidential Account for the benefit of the AP. AP Representatives will be broker-dealers. An AP must be a depository trust company participant that has executed an authorized participant agreement (''Participant Agreement'') with the Distributor with respect to the creation and redemption of Creation Units and Redemption Units and formed a Confidential Account with an AP

[9] The Exchange represents that, for initial and continued listing, each Fund will be in compliance with Rule 10A–3 under the Act. *See* 17 CFR 240.10A–3.

[10] Pursuant to the Exemptive Order, the only permissible investments for a Fund are the following that trade on a U.S. exchange contemporaneously with the Funds' Shares: Exchange-traded funds (''ETFs''), exchange-traded notes, exchange-listed common stocks, exchange-traded preferred stocks, exchange-traded American Depositary Receipts, exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metals trusts, exchange-traded currency trusts and exchange-traded futures, as well as cash and cash equivalents (short-term U.S. Treasury securities, government money market funds, and repurchase agreements). All of the equity instruments or futures held by a Fund will be traded on an exchange that is a member of the Intermarket Surveillance Group (''ISG'') or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

[11] *See id.*

[12] Rule 8.900–E(c)(6) provides that the term ''Creation Unit'' means a specified minimum number of Managed Portfolio Shares issued by an Investment Company at the request of an Authorized Participant in return for a designated portfolio of instruments and/or cash.

[13] Rule 8.900–E(c)(7) provides that the term ''Redemption Unit'' means a specified minimum number of Managed Portfolio Shares that may be redeemed to an Investment Company at the request of an Authorized Participant in return for a portfolio of instruments and/or cash.

[14] Rule 8.900–E(c)(4) provides that the term ''Confidential Account'' means an account owned by an Authorized Participant and held with an AP Representative on behalf of the Authorized Participant. The account will be established and governed by contractual agreement between the AP Representative and the Authorized Participant solely for the purposes of creation and redemption, while keeping confidential the Creation Basket constituents of each series of Managed Portfolio Shares, including from the Authorized Participant. The books and records of the Confidential Account will be maintained by the AP Representative on behalf of the Authorized Participant.

[15] Rule 8.900–E(c)(3) provides that the term ''AP Representative'' means an unaffiliated broker-dealer, with which an Authorized Participant has signed an agreement to establish a Confidential Account for the benefit of such Authorized Participant, that will deliver or receive, on behalf of the Authorized Participant, all consideration to or from the Investment Company in a creation or redemption. An AP Representative will not be permitted to disclose the Creation Basket to any person, including the Authorized Participants.

Representative for its benefit in accordance with the terms of the Participant Agreement. For purposes of creations or redemptions, all transactions will be effected through the respective AP's Confidential Account, for the benefit of the AP, without disclosing the identity of such securities to the AP.

Each AP Representative will be given, before the commencement of trading each Business Day (as defined below), the Creation Basket (as described below) for that day. This information will permit an AP that has established a Confidential Account with an AP Representative to instruct the AP Representative to buy and sell positions in the portfolio securities to permit creation and redemption of Creation Units and Redemption Units. Shares of each Fund will be issued and redeemed in Creation Units and Redemption Units. A Creation Unit and Redemption Unit consists of 10,000 shares. The size of Creation Units and Redemption Units is subject to change. The Funds will offer and redeem Creation Units and Redemption Units on a continuous basis at the net asset value (''NAV'') per Share next determined after receipt of an order in proper form. The NAV per Share of each Fund will be determined as of the close of regular trading on the Exchange on each day that the Exchange is open (a ''Business Day''). The Funds will sell and redeem Creation Units and Redemption Units only on Business Days.

In order to keep costs low and permit each Fund to be as fully invested as possible, Shares will be purchased and redeemed from the respective Fund in Creation Units and Redemption Units and generally on an in-kind basis. Accordingly, except where the purchase or redemption is exclusively made in cash under the circumstances permitted in the Exemptive Application, APs will be required to purchase Creation Units by accepting an in-kind deposit of a designated portfolio of securities (''Deposit Securities''), and APs redeeming their Shares will receive from the Fund an in-kind transfer of a designated portfolio of securities (''Fund Securities'') through the AP Representative into their Confidential Account.[16] On any given Business Day, the names and quantities of the instruments that constitute the Deposit Securities and the names and quantities of the instruments that constitute the Fund Securities will be identical, and these instruments may be referred to, in the case of either a purchase or a redemption, as the ''Creation Basket.''

Placement of Purchase Orders

Each Fund will issue Shares through the Distributor on a continuous basis at NAV. The Exchange represents that the issuance of Shares will operate in a manner substantially similar to that of other ETFs. Each Fund will issue Shares only at the NAV per Share next determined after an order in proper form is received. The Distributor will furnish acknowledgements to those placing such orders that the orders have been accepted, but the Distributor may reject any order which is not submitted in proper form, as described in each Fund's prospectus or Statement of Additional Information (''SAI'').

The NAV of each Fund is expected to be determined once each Business Day as of the close of the regular trading session on the NYSE (normally 4:00 p.m. E.T.) (the ''Valuation Time''). To initiate a purchase of Shares, an AP must submit to the Distributor an irrevocable order to purchase such Shares after the most recent prior Valuation Time. In purchasing the necessary securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket.

Each Fund will establish a cut-off time (''Order Cut-Off Time'') for purchase orders in proper form. Generally, all orders to purchase Creation Units must be received by the Distributor no later than the Order Cut-Off Time on the date such order is placed (''Transmittal Date'') in order for the purchaser to receive the NAV per Share determined on the Transmittal Date. As with all existing ETFs, if there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the ''Balancing Amount'').

Purchases of Shares will be settled in-kind and/or cash for an amount equal to the applicable NAV per Share purchased plus applicable transaction fees.[17] Other than the Balancing Amount, a Fund will substitute cash only under exceptional circumstances and as set forth under the Fund's policies and procedures governing the composition of Creation Baskets.

Authorized Participant Redemption

The Shares may be redeemed to a Fund in Redemption Unit size or multiples thereof as described below. Redemption orders of Redemption Units must be placed by or through an AP (''AP Redemption Order'') in proper form. Redemption Units of a Fund will be redeemable at their NAV per Share next determined after receipt of a request for redemption by the Trust in the manner specified below before the Order Cut-Off Time. To initiate an AP Redemption Order, an AP must submit to the Distributor an irrevocable order to redeem such Redemption Unit no later than the Order Cut-Off Time on the Transmittal Date. A transaction fee may be imposed to offset costs associated with redemption orders.

In the case of a redemption, the AP would enter into an irrevocable redemption order, and then the applicable Fund would instruct its custodian to deliver the Fund Securities to the appropriate Confidential Account. The Authorized Participant would direct the AP Representative on when that day to liquidate those securities. As with the purchase of securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket.

Redemptions will occur primarily in-kind, although redemption payments may also be made partly or wholly in cash. The Participant Agreement signed by each AP will require establishment of a Confidential Account to receive distributions of securities in-kind upon redemption. Each AP will be required to open a Confidential Account with an AP Representative in order to facilitate orderly processing of redemptions.

Net Asset Value

Each Fund calculates its NAV once each business day as of the regularly scheduled close of trading on the New York Stock Exchange, normally 4:00 p.m. Eastern Time. The NAV of each Fund is computed by (i) taking the current market value of its total assets, (ii) subtracting any liabilities, and (iii) dividing the result by the total number of shares outstanding.

In computing each Fund's NAV, the Fund's securities holdings are valued based on their last readily available market price. Securities for which such information is readily available are generally valued at the last reported

[16] According to the Registration Statement, the Funds must comply with the federal securities laws in accepting Deposit Securities and satisfying redemptions with Fund Securities, including that the Deposit Securities and Fund Securities are sold in transactions that would be exempt from registration under the 1933 Act.

[17] To the extent that a Fund allows creations or redemptions to be conducted in cash, such transactions will be effected in the same manner for all APs transacting in cash.

sales price, the official closing price as reported by an independent pricing service on the primary market or exchange on which they are traded, or, in the absence of reported sales, at the most recent bid price. If market prices are unavailable or a Fund thinks that they are unreliable, or when the value of a security has been materially affected by events occurring after the relevant market closes, the Fund will price those securities at fair value as determined in good faith using methods approved by the Fund's Board.

More information about the valuation of each Fund's holdings can be found in the SAI.

Information showing the number of days that the market price of each Fund's Shares was greater than the Fund's NAV (*i.e.,* at a premium) or less than the Fund's NAV (*i.e.,* at a discount) for various time periods will be available on the Funds' website at *www.cambiar.com.*

Availability of Information

The Funds' website, *www.cambiar.com,* will include a form of the prospectus for each Fund that may be downloaded. The Funds' website will include additional quantitative information updated on a daily basis, including, on a per share basis for each Fund, the prior Business Day's NAV, market closing price, the bid/ask spreads at the time of calculation of such NAV (the ''Bid/Ask Price''),[18] and a calculation of the premium or discount of the market closing price or Bid/Ask Price against the NAV. The website and information will be publicly available at no charge.

Form N–PORT requires reporting of a Fund's complete portfolio holdings on a position-by-position basis on a quarterly basis within 60 days after fiscal quarter end. Investors can obtain a Fund's SAI, its shareholder reports, its Form N–CSR, filed twice a year, and its Form N–CEN, filed annually. Each Fund's SAI and shareholder reports are available free upon request from the Investment Company, and those documents and the Form N–PORT, Form N–CSR, and Form N–CEN may be viewed onscreen or downloaded from the Commission's website at *www.sec.gov.*

Information regarding market price and trading volume of the Shares will be continually available to market participants on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the Verified Intraday Indicative Value (''VIIV''), as defined in Rule 8.900–E(c)(2),[19] will be widely disseminated by the Reporting Authority [20] and/or one or more major market data vendors in one second intervals during the Exchange's Core Trading Session.

Dissemination of the VIIV

With respect to trading of the Shares, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for a Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on a Fund's actual portfolio holdings, (2) the securities in which a Fund plans to invest are generally highly liquid and actively traded and trade at the same time as the Fund and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The VIIV will be widely disseminated by the Reporting Authority and/or by one or more major market data vendors in one second intervals during the Core Trading Session and will be disseminated to all market participants at the same time. The VIIV is based on the current market value of the securities in a Fund's portfolio that day. The methodology for calculating the VIIV will be available on the Funds' website. The VIIV is intended to provide investors and other market participants with a highly correlated per Share value of the underlying portfolio that can be compared to the current market price. Therefore, under normal circumstances the VIIV would be effectively a near real time approximation of each Fund's NAV, which is computed only once a day, and is available free of charge from one or more market data vendors.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of a Fund.[21] Trading in Shares of a Fund will be halted if the circuit breaker parameters in Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to Rule 8.900–E(d)(2)(C), which sets forth circumstances under which Shares of a Fund will be halted.

Specifically, Rule 8.900–E(d)(2)(C)(i) provides that the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Managed Portfolio Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of Managed Portfolio Shares inadvisable. These may include: (a) The extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (b) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[22]

Rule 8.900–E(d)(2)(C)(ii) provides that, if the Exchange becomes aware

[18] The Bid/Ask Price of a Fund's Shares is determined using the mid-point between the current national best bid and offer at the time of calculation of such Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Funds or their service providers.

[19] Rule 8.900–E(c)(2) provides that the term ''Verified Intraday Indicative Value'' is the indicative value of a Managed Portfolio Share based on all of the holdings of a series of Managed Portfolio Shares as of the close of business on the prior business day and, for corporate actions, based on the applicable holdings as of the opening of business on the current business day, priced and disseminated in one second intervals during the Core Trading Session by the Reporting Authority.

[20] Rule 8.900–E(c)(8) provides that the term ''Reporting Authority'' in respect of a particular series of Managed Portfolio Shares means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists a particular series of Managed Portfolio Shares (if the Exchange is trading such series pursuant to unlisted trading privileges), as the official source for calculating and reporting information relating to such series, including, but not limited to, the NAV, the VIIV, or other information relating to the issuance, redemption, or trading of Managed Portfolio Shares. A series of Managed Portfolio Shares may have more than one Reporting Authority, each having different functions.

[21] *See* Rule 7.12–E.

[22] The Exemptive Application provides that the Investment Company or their agent will request that the Exchange halt trading in the applicable series of Managed Portfolio Shares where: (i) The intraday indicative values calculated by the calculation engines differ by more than 25 basis points for 60 seconds in connection with pricing of the VIIV; or (ii) holdings representing 10% or more of a series of Managed Portfolio Shares' portfolio have become subject to a trading halt or otherwise do not have readily available market quotations. Any such requests will be one of many factors considered in order to determine whether to halt trading in a series of Managed Portfolio Shares, and the Exchange retains sole discretion in determining whether trading should be halted. As provided in the Exemptive Application, each series of Managed Portfolio Shares would employ a pricing verification agent to continuously compare two intraday indicative values during regular trading hours in order to ensure the accuracy of the VIIV.

that: (i) The VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one second intervals, as required; (ii) the NAV with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time; (iii) the holdings of a series of Managed Portfolio Shares are not made available on at least a quarterly basis as required under the 1940 Act; or (iv) such holdings are not made available to all market participants at the same time (except as otherwise permitted under the currently applicable exemptive order or no-action relief granted by the Commission or Commission staff to the Investment Company with respect to the series of Managed Portfolio Shares), it will halt trading in such series until such time as the VIIV, the net asset value, or the holdings are available, as required.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the Exchange in all trading sessions in accordance with Rule 7.34–E(a). As provided in Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001. A minimum of 100,000 Shares of each Fund will be outstanding at the commencement of trading on the Exchange.

The Shares will conform to the initial and continued listing criteria under Rule 8.900–E, as well as all terms in the Exemptive Order. The Exchange will obtain a representation from the issuer of the Shares of each Fund that the NAV per Share of each Fund will be calculated daily and will be made available to all market participants at the same time.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products. As part of these surveillance procedures and consistent with Rule 8.900–E(b)(3) and 8.900–E(d)(2)(B), the Adviser will upon request make available to the Exchange and/or FINRA, on behalf of the Exchange, the daily portfolio holdings of a Fund. The issuer of the Shares of each Fund will be required to represent to the Exchange that it will advise the Exchange of any failure by a Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 5.5–E(m).

FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, will communicate as needed regarding trading in the Shares and certain exchange-traded instruments with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain exchange-traded instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees. FINRA also generally prohibits its employees from disseminating or disclosing any non-public information obtained in the course of his or her employment.[23]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[24] in general, and furthers the objectives of Section 6(b)(5) of the Act,[25] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that this proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Funds would meet each of the rules relating to listing and trading of Managed Portfolio Shares. To the extent that a Fund is not in compliance with such rules, the Exchange would either prevent the Fund from listing and trading on the Exchange or commence delisting procedures under Rule 8.900–E(d)(2)(B). Specifically, the Exchange would consider the suspension of trading, and commence delisting proceedings under Rule 8.900–E(d)(2)(B), of a Fund under any of the following circumstances: (a) If, following the initial twelve-month period after commencement of trading on the Exchange, there are fewer than 50 beneficial holders of the Fund; (b) if the Exchange has halted trading in a Fund because the VIIV is interrupted pursuant to Rule 8.900–E(d)(2)(C)(ii) and such interruption persists past the trading day in which it occurred or is no longer available; (c) if the Exchange has halted trading in a Fund because the net asset value with respect to such Fund is not disseminated to all market participants at the same time, the holdings of such Fund are not made available on at least a quarterly basis as required under the 1940 Act, or such holdings are not made available to all market participants at the same time pursuant to Rule 8.900–E(d)(2)(C)(ii) and such issue persists past the trading day in which it occurred; (d) if the Exchange has halted trading in Shares of a Fund pursuant to Rule 8.900–E(d)(2)(C)(i) and such issue persists past the trading day in which it occurred; (e) if a Fund has failed to file any filings required by the Commission or if the Exchange is aware that a Fund is not in compliance with the conditions of any currently applicable exemptive order or no-action relief granted by the Commission or Commission staff with respect to the Fund; (f) if any of the continued listing requirements set forth in Rule 8.900–E are not continuously maintained; (g) if any of the statements of representations regarding (a) the description of the portfolio, (b) limitations on portfolio holdings, or (c) the applicability of Exchange listing rules as specified herein to permit the listing and trading of a Fund, are not continuously maintained; or (h) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

As discussed above, the Adviser is not registered as a broker-dealer and is not affiliated with any broker-dealer In the event that (a) the Adviser or sub-adviser

[23] *See* Securities Exchange Act Release No. 89663 (August 25, 2020), 85 FR 53868 (August 31, 2020) (SR–NYSEArca–2020–48) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of Gabelli ETFs Under Rule 8.900–E, Managed Portfolio Shares).

[24] 15 U.S.C. 78f(b).

[25] 15 U.S.C. 78f(b)(5).

becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, the Adviser will implement and maintain a fire wall with respect to personnel of the broker-dealer or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and/or Creation Basket. Any person related to the Adviser or the Trust who makes decisions pertaining to a Fund's portfolio composition or that has access to information regarding a Fund's portfolio or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio or changes thereto and the Creation Basket.

In addition, Rule 8.900–E(b)(5) requires that any person or entity, including an AP Representative, custodian, Reporting Authority, distributor, or administrator, who has access to non-public information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket, must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket. Any person or entity who has access to information regarding a Fund's portfolio composition or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the portfolio or changes thereto or the Creation Basket.

The Exchange further believes that Rule 8.900–E is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Shares of the Funds because it provides meaningful requirements about both the data that will be made publicly available about the Shares, as well as the information that will only be available to certain parties and the controls on such information. Specifically, the Exchange believes that the requirements related to information protection set forth in Rule 8.900–E(b)(5) will act as a safeguard against misuse and improper dissemination of information related to a Fund's portfolio composition, the Creation Basket, or changes thereto. The requirement that any person or entity implement procedures to prevent the use and dissemination of material non-public information regarding the portfolio or Creation Basket will act to prevent any individual or entity from sharing such information externally and the internal ''fire wall'' requirements applicable where an entity is a registered broker-dealer or affiliated with a broker-dealer will act to make sure that no entity will be able to misuse the data for their own purposes. Accordingly, the Exchange believes that this proposal is designed to prevent fraudulent and manipulative acts and practices.

The Exchange further believes that the proposal is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Shares of the Funds and to promote just and equitable principles of trade and to protect investors and the public interest because the Exchange would halt trading under certain circumstances under which trading in the Shares of a Fund may be inadvisable. Specifically, trading in the Shares will be subject to Rule 8.900–E(d)(2)(C)(i), which provides that the Exchange may consider all relevant factors in exercising its discretion to halt trading in a Fund. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of Managed Portfolio Shares inadvisable. These may include: (a) The extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (b) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[26] Additionally, trading in the Shares will be subject to Rule 8.900–E(d)(2)(C)(ii), which provides that the Exchange would halt trading where the Exchange becomes aware that: (a) The VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one second intervals, as required; (b) the net asset value with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time; (c) the holdings of a series of Managed Portfolio Shares are not made available on at least a quarterly basis as required under the 1940 Act; or (d) such holdings are not made available to all market participants at the same time (except as otherwise permitted under the currently applicable exemptive order or no-action relief granted by the Commission or Commission staff to the Investment Company with respect to the series of Managed Portfolio Shares). The Exchange would halt trading in such Shares until such time as the VIIV, the NAV, or the holdings are available, as required.

With respect to the proposed listing and trading of Shares of the Funds, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Rule 8.900–E.[27] Each Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application and Exemptive Order.[28] As noted above, FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, will communicate as needed regarding trading in the Shares and the underlying exchange-traded instruments with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, may obtain trading information regarding trading such instruments from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the underlying exchange-traded instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

With respect to trading of Shares of the Funds, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for a Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on a Fund's actual portfolio holdings, (2) the securities in which the Funds plan to invest are generally highly liquid and actively traded and trade at the same time as the Funds and therefore generally have accurate real time pricing available, and (3) market participants

[26] *See supra* note 22.

[27] The Exchange represents that, for initial and continued listing, each Fund will be in compliance with Rule 10A–3 under the Act. *See* 17 CFR 240.10A–3.

[28] *See supra* note 10.

will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation that the NAV per Share of the Funds will be calculated daily and that the NAV will be made available to all market participants at the same time. Investors can also obtain a Fund's SAI, its shareholder reports, its Form N–CSR (filed twice a year), and its Form N–CEN (filed annually). A Fund's SAI and shareholder reports will be available free upon request from the applicable Fund, and those documents and the Form N–PORT, Form N–CSR, and Form N–CEN may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov.* In addition, a large amount of information will be publicly available regarding the Funds and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line. Information regarding the VIIV will be widely disseminated in one second intervals throughout the Core Trading Session by the Reporting Authority and/or one or more major market data vendors. The website for the Funds will include a prospectus for the Funds that may be downloaded, and additional data relating to NAV and other applicable quantitative information, updated on a daily basis. Moreover, prior to the commencement of trading, the Exchange will inform its members in an Information Bulletin of the special characteristics and risks associated with trading the Shares.

In addition, as noted above, investors will have ready access to the VIIV, and quotation and last sale information for the Shares. The Shares will conform to the initial and continued listing criteria under Rule 8.900–E. Each Fund's investments, including derivatives, will be consistent with its investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, a Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2X or −3X) of the Fund's benchmark.

The Exchange also believes that the proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of actively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the VIIV and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change would permit the listing and trading of additional actively-managed exchange-traded products, thereby promoting competition among exchange-traded products to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[29] and Rule 19b–4(f)(6) thereunder.[30]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[31] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the Commission has approved proposed rule changes to permit listing and trading on the Exchange of Managed Portfolio Shares similar to the Funds.[32] The proposed listing rule for the Funds raises no novel legal or regulatory issues. For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[33]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2021–54 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2021–54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will

[29] 15 U.S.C. 78s(b)(3)(A).

[30] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[31] 17 CFR 240.19b–4(f)(6)(iii).

[32] *See supra* note 5.

[33] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2021–54 and should be submitted on or before August 13, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–15655 Filed 7–22–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92437; File No. SR–NSCC–2021–009]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of a Proposed Rule Change To Modify the Rules & Procedures of National Securities Clearing Corporation in Connection With the Implementation of Section 1446(f) of the Internal Revenue Code of 1986

July 19, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 14, 2021, National Securities Clearing Corporation (''NSCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to the Rules & Procedures (''Rules'')[3] of NSCC in connection with the implementation of section 1446(f) of the Internal Revenue Code of 1986, as amended, that was enacted as part of the Tax Cuts and Jobs Act of 2017,[4] and the Treasury Regulations or other official interpretations thereunder, as in effect from time to time (collectively ''Section 1446(f)''), as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend the Rules in connection with the implementation of Section 1446(f). The proposed rule change also includes technical changes.

(i) Background

Section 1446(f) and Section 1446(f) Withholding

Section 1446(f) was enacted on December 22, 2017, as part of the Tax Cuts and Jobs Act of 2017,[5] and the U.S. Treasury Department (''Treasury Department'') finalized and issued various implementing regulations on October 7, 2020,[6] including the tax withholding required pursuant to Treasury Regulation Section 1.1446(f)–4(a)[7] upon the transfer of an interest in a publicly traded partnership (''Section 1446(f) Withholding''). It is NSCC's understanding that Section 1446(f) Withholding is designed to ensure any non-U.S. person (either individual or entity) appropriately files a U.S. federal income tax return following the sale or disposition of its interest in certain partnerships.

Section 1446(f) generally imposes a ten percent (10%) withholding tax on the payment of gross proceeds arising from the sale or other disposition by a non-U.S. person of an interest in certain partnerships that are engaged in a U.S. trade or business.[8] In such a case, a tax withholding obligation is imposed on the buyer of the partnership interest, who is required to remit the withheld tax amount to the U.S. Internal Revenue Service (''IRS''), unless or to the extent an applicable exception applies.[9] The buyer obligated to withhold the 10% tax is liable for any amount that it underwithheld, plus associated interest and penalties.[10]

On October 7, 2020, the IRS and Treasury Department issued final regulations under Section 1446(f) (the ''Final Regulations''),[11] which require Section 1446(f) Withholding on partnerships that are publicly traded on exchanges (''PTPs'') in respect of transfers that occur on or after January 1, 2022. The Final Regulations provided U.S. clearing organizations, such as NSCC, an exemption from the obligation to perform the Section 1446(f) Withholding at this time.[12] This exemption is premised in part on the IRS and Treasury Department's understanding that all of NSCC's non-U.S. Members are of the types of entities that are permitted to perform the Section 1446(f) Withholding themselves.[13] [14] NSCC currently clears and settles all transactions on a netted basis. If NSCC were required to perform Section 1446(f) Withholding, NSCC would have to clear and settle transfers

[34] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms not defined herein are defined in the Rules, *available at http://www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.*

[4] Public Law 115–97 (2017), section 864(c)(8).

[5] *Id.*

[6] Withholding of Tax and Information Reporting With Respect to Interests in Partnerships Engaged in a U.S. Trade or Business, 85 FR 76910 (Nov. 30, 2020).

[7] 26 CFR 1.1446–4(a).

[8] I.R.C. Section 1446(f).

[9] *Id.*

[10] *Id.*

[11] *See* note 6.

[12] *See* note 6, at 76922.

[13] *Id.*

[14] The Final Regulations provided that if a direct clearing member of a U.S. clearing organization is not of a type of entity permitted to perform Section 1446(f) Withholding, the IRS and Treasury Department will issue proposed guidance that would revise the Final Regulations to require Section 1446(f) Withholding by U.S. clearing organization on such direct clearing member. *Id.*

of PTP interest on a gross basis, which may be disruptive to the efficiency and liquidity of the trading of PTP interests in the capital markets, as noted in the Final Regulations.[15]

Currently, all of NSCC's non-U.S. Members are of the types of entities permitted to perform the Section 1446(f) Withholding themselves either because (i) they are the types of entities allowed to perform U.S. tax withholdings pursuant to applicable Treasury Regulations or (ii) they have entered into the requisite agreements with the IRS that allow them to perform U.S. tax withholdings (commonly known as the Qualified Intermediary Agreements). Nearly all such Members have historically accepted the responsibility to perform all U.S. tax withholdings in respect of their NSCC accounts, and it is NSCC's understanding that they would continue do the same for Section 1446(f) Withholding.

(ii) Proposed Rule Changes

In order to comport with the legislative understanding underlying the Section 1446(f) Withholding exemption, NSCC is proposing amendments to its Rules to ensure that all NSCC FFI Members that are Members would accept the responsibility to perform the Section 1446(f) Withholding.[16]

Rule 1 (Definitions and Descriptions)

NSCC is proposing to add the following terms and definitions in Rule 1 (Definitions and Descriptions), as described below.

The term ''Section 1446(f)'' would mean section 1446(f) of the Code and the related Treasury Regulations or other official interpretations thereof, as in effect from time to time.

The term ''Section 1446(f) Withholding'' would mean the tax withholding required pursuant to Treasury Regulation Section 1.1446(f)–4(a), upon the transfer of an interest in a publicly traded partnership. As defined, ''Section 1446(f) Withholding'' would not apply to any tax withholding required on distributions made by such a partnership.

The term ''Section 1446(f) Withholding Agent'' would mean an FFI Member that is a Member and has certified to NSCC that Section 1446(f) Withholding would not apply to any Gross Credit Balance of such FFI Member by providing to NSCC a Tax Certification (as defined below and in the proposed rule text).

The term ''Section 1446(f) Withholding Compliance Date'' would mean January 1, 2022 or, if the commencement of Section 1446(f) Withholding is delayed beyond January 1, 2022 under Section 1446(f), two calendar months plus one calendar day before such delayed effective date.

NSCC is proposing to delete ''FATCA Certification'' and replace it with ''Tax Certification.'' As proposed, the term ''Tax Certification'' would mean an executed copy of the relevant tax form required by the IRS, as in effect from time to time, that each Member and Limited Member (or applicant to become such) shall provide from time to time to NSCC as set forth under the Rules and Procedures.

NSCC is also proposing two technical changes. First, NSCC is proposing to delete ''FATCA Compliance Date'' from Rule 1 because it would no longer be used in the Rules under the proposal. Second, NSCC is proposing to delete the definition of ''Code'' that is currently embedded within the definition of ''FATCA'' and add it as a standalone definition entry in Rule 1 so that it can be readily identified.

Rule 2 (Members and Limited Members)

NSCC is proposing to retitle Section 4(iii) of Rule 2 (Members and Limited Members) from ''FATCA'' to ''FATCA and Section 1446(f).''

NSCC is also proposing to delete a reference to FATCA Compliance Date in the first paragraph of Section 4(iii) of Rule 2 because it is no longer relevant given FATCA is already in effect. In addition, NSCC is proposing to add a paragraph to Section 4(iii) of Rule 2 to require that, beginning on the Section 1446(f) Withholding Compliance Date, each FFI Member that is a Member must agree not to conduct any transaction or activity through NSCC if such FFI Member is not a Section 1446(f) Withholding Agent, unless such requirement has been explicitly waived in writing by NSCC with respect to the specific FFI Member.[17]

In addition, NSCC is proposing to revise the last two paragraphs in Section 4(iii) of Rule 2 by changing FATCA Certification to Tax Certification, deleting a reference to FATCA, as well as adding references to Section 1446(f) Withholding Agent. As revised, each FFI Member is required to certify and periodically recertify to NSCC that such FFI Member is FATCA Compliant and/or a Section 1446(f) Withholding Agent, as applicable, by providing to NSCC a Tax Certification. In addition, an FFI Member shall indemnify NSCC for any loss, liability or expense sustained by NSCC as a result of such FFI Member failing to be FATCA Compliant or a Section 1446(f) Withholding Agent.

Rule 2A (Initial Membership Requirements)

NSCC is proposing to revise Section 1.B and 1.C of Rule 2A (Initial Membership Requirements) by including a reference to Section 1446(f) Withholding Agent and replacing FATCA Certification with Tax Certification, respectively. As proposed, Section 1.B of Rule 2A would provide that any applicant that shall be an FFI Member must be FATCA Compliant and/or a Section 1446(f) Withholding Agent, as applicable. In addition, as proposed, Section 1.C of Rule 2A would provide that, as part of its membership application, each applicant shall complete and deliver to NSCC a Tax Certification instead of a FATCA Certification. NSCC is also proposing a technical change by deleting an extraneous comma from Section 1.C of Rule 2A.

Rule 2B (Ongoing Membership Requirements and Monitoring)

NSCC is proposing to revise Section 2.B.(c) of Rule 2B (Ongoing Membership Requirements and Monitoring) by removing a reference to FATCA Compliance Date because it is no longer relevant given FATCA is already in effect. NSCC is also proposing to replace FATCA Certification with Tax Certification in Section 2.B.(c)(i) of Rule 2B and change two days to two calendar days in that section. Lastly, NSCC is proposing to add a new sentence to Section 2.B.(c) of Rule 2B that provides, beginning on the Section 1446(f) Withholding Compliance Date, each FFI Member that is a Member shall inform NSCC, both orally and in writing, if it has reason to know that it is not, or will not be, a Section 1446(f) Withholding Agent within two calendar days of knowledge thereof.

Rule 53 (Alternative Investment Product Services and Members)

NSCC is proposing to revise Sections 1(d)(iv) and 5(e)(i) of Rule 53 (Alternative Investment Product Services and Members) by replacing references of FATCA Certification with Tax Certification. In addition, NSCC is

[15] *See* note 6, at 76922.

[16] It is NSCC's understanding that, based on the types of services that NSCC provides to Limited Members, notwithstanding any exemption, NSCC would not need to perform Section 1446(f) Withholding with respect to Limited Members' activities at NSCC.

[17] NSCC may waive this requirement from time to time with respect to a specific FFI Member if the FFI Member is unable to satisfy the requirement due to unusual and/or extraordinary circumstances, such as an unanticipated regulatory change in the tax withholding requirement or if the FFI Member is rectifying an unexpected change in its tax withholding status.

proposing to retitle Section 5(e) of Rule 53 as ''Tax Considerations—AIP Settling Sub-Accounts.''

Addendum O (Admission of Non-U.S. Entities as Direct NSCC Members)

NSCC is proposing to revise Addendum O (Admission of Non-U.S. Entities as Direct NSCC Members) to include requirements associated with Section 1446(f) Withholding. As proposed, NSCC would require each non-U.S. entity that is applying to become a Member or certain Limited Member to (i) agree not to conduct any transaction or activity through NSCC if the non-U.S. entity is not FATCA Compliant and/or is not a Section 1446(f) Withholding Agent, as applicable and (ii) indemnify NSCC for any loss, liability or expense sustained by NSCC as a result of the non-U.S. entity failing to be FATCA Compliant or a Section 1446(f) Withholding Agent. NSCC is also proposing to retitle the second bullet in Addendum O to ''FACTA Compliance, Section 1446(f) Withholding, and Tax Certification.'' In addition, NSCC is proposing to remove the reference to FATCA Compliance Date from the second bullet in Addendum O because it is no longer relevant given FATCA is already in effect. Furthermore, NSCC is proposing to revise the second bullet in Addendum O by (i) adding references to Section 1446(f) Withholding Compliance Date and Section 1446(f) Withholding Agent and (ii) replacing FATCA Certification with Tax Certification. As proposed, the second bullet in Addendum O would provide, in part, that each non-U.S. entity that is applying to become a Member or certain Limited Member must be at all times FATCA Compliant and, beginning on the Section 1446(f) Withholding Compliance Date, be a Section 1446(f) Withholding Agent, if applicable, and must certify and recertify to NSCC that it is FATCA Compliant and/or a Section 1446(f) Withholding Agent, as applicable, by providing to NSCC a Tax Certification, unless such requirements have been explicitly waived in writing by NSCC.

(iii) Member Outreach

Beginning in December 2020, NSCC conducted ongoing outreach to non-U.S. Members that are not currently performing U.S. tax withholding in order to provide them with notice of the proposed changes. As of the date of this filing, no written comments relating to the proposed changes have been received in response to this outreach. The Commission will be notified of any written comments received.

2. Statutory Basis

NSCC believes this proposal is consistent with Section 17A(b)(3)(F) [18] of the Act for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.[19] NSCC believes that the proposed rule change to amend the Rules in connection with the implementation of Section 1446(f) is consistent with Section 17A(b)(3)(F) of the Act. This is because the proposed rule change is designed to ensure that all NSCC FFI Members that are Members would accept the responsibility to perform the Section 1446(f) Withholding, consistent with the understanding of the IRS and Treasury Department as expressed in the Final Regulations.[20]

As mentioned above, the Final Regulations provided NSCC an exemption from the obligation to perform Section 1446(f) Withholding at this time.[21] However, the Final Regulations also provided that if a direct clearing member of a U.S. clearing organization is not of a type of entity permitted to perform Section 1446(f) Withholding, the IRS and Treasury Department will issue proposed guidance that would revise the Final Regulations to require Section 1446(f) Withholding by U.S. clearing organization, such as NSCC, on such direct clearing member.[22] If the IRS and Treasury Department were to revise the Final Regulations and revoke NSCC's exemption, NSCC would be required to clear and settle each transfer of PTP interest on a gross basis in order to perform Section 1446(f) Withholding on such transfer. Given that NSCC currently clears and settles all transactions on a netted basis, if NSCC has to clear and settle transfers of PTP interest on a gross basis, it may be disruptive to the efficiency and liquidity of the trading of PTP interests in the capital markets, as noted in the Final Regulations.[23]

In order to be consistent with the understanding of the IRS and Treasury Department which NSCC's Section 1446(f) exemption was premised upon,[24] NSCC is proposing that, unless waived by NSCC, beginning on the Section 1446(f) Withholding Compliance Date, each FFI Member that is a Member would have to agree not to conduct any transaction or activity through NSCC if such FFI Member is not a Section 1446(f) Withholding Agent. In addition, each FFI Member that is a Member would have to provide periodic certifications to NSCC regarding its Section 1446(f) Withholding Agent status. Taken together, these requirements would help to ensure that all NSCC FFI Members that are Members would accept their responsibility to perform the Section 1446(f) Withholding (*i.e.,* be a Section 1446(f) Withholding Agent).

By ensuring that all NSCC FFI Members that are Members would accept their responsibility to perform the Section 1446(f) Withholding, NSCC believes it would minimize the likelihood that the IRS and Treasury Department would revise the Final Regulations to revoke NSCC's Section 1446(f) exemption. Having the IRS and the Treasury Department continue to exempt NSCC from Section 1446(f) Withholding would enable NSCC to continue to clear and settle all transactions (including transfers of PTP interest) on a netted basis and avoid any potential disruption to the efficiency and liquidity of the trading of PTP interests in the capital market. By avoiding any potential disruption to the efficiency and liquidity of the trading of PTP interest in the capital market, the proposed rule change would help to promote the prompt and accurate clearance and settlement of transactions. As such, NSCC believes the proposed rule change to amend the Rules in connection with the implementation of Section 1446(f) is consistent with Section 17A(b)(3)(F) of the Act.[25]

NSCC believes the proposal to make technical changes to the Rules is also consistent with Section 17A(b)(3)(F) of the Act.[26] The proposed technical changes to the Rules would help ensure that the Rules remain accurate and clear to Members. Having accurate and clear Rules would help Members to better understand their rights and obligations regarding NSCC's clearance and settlement services. NSCC believes that when Members better understand their rights and obligations regarding NSCC's clearance and settlement services, they can act in accordance with the Rules. NSCC believes that better enabling Members to comply with the Rules would promote the prompt and accurate clearance and settlement of securities transactions by NSCC. As such, NSCC believes the proposal to make technical

[18] 15 U.S.C. 78q–1(b)(3)(F).

[19] *Id.*

[20] *See* note 6, at 76922.

[21] *Id.*

[22] *Supra* note 14.

[23] *See* note 6, at 76922.

[24] *Id.*

[25] 15 U.S.C. 78q–1(b)(3)(F).

[26] *Id.*

changes to the Rules is consistent with Section 17A(b)(3)(F) of the Act.[27]

(B) Clearing Agency's Statement on Burden on Competition

NSCC believes that the proposed rule change to amend the Rules in connection with the implementation of Section 1446(f) could impose a burden on competition because the change could impose a cost on firms that currently do not do U.S. tax withholding by requiring them to perform the Section 1446(f) Withholding by the Section 1446(f) Withholding Compliance Date. However, NSCC believes any such burden is necessary and appropriate. Specifically, NSCC believes that any burden on competition that is created by the proposed rule change would be necessary in furtherance of the purposes of Section 17A(b)(3)(F) of the Act. As described above, the proposed rule change is designed to ensure that all NSCC FFI Members that are Members would accept the responsibility to perform the Section 1446(f) Withholding, consistent with the understanding of the IRS and Treasury Department as expressed in the Final Regulations.[28] By ensuring that all NSCC FFI Members that are Members would accept their responsibility to perform the Section 1446(f) Withholding, NSCC believes it would minimize the likelihood that the IRS and Treasury Department would revise the Final Regulations to revoke NSCC's Section 1446(f) exemption. Having the IRS and the Treasury Department continue to exempt NSCC from Section 1446(f) Withholding would enable NSCC to continue to clear and settle all transactions (including transfers of PTP interest) on a netted basis and avoid any potential disruption to the efficiency and liquidity of the trading of PTP interests in the capital market. By avoiding any potential disruption to the efficiency and liquidity of the trading of PTP interest in the capital market, the proposed rule change would help to promote the prompt and accurate clearance and settlement of transactions, consistent with Section 17A(b)(3)(F) of the Act.[29] NSCC also believes that any burden that is created by the proposed rule change would be appropriate. This is because the proposed change would be limited to Section 1446(f) Withholding and associated certification and is also consistent with the understanding of the IRS and Treasury Department as expressed in the Final Regulations.[30]

NSCC does not believe the proposal to make technical changes to the Rules would impact competition. The changes would apply equally to all Members and would not affect Members' rights and obligations. As such, NSCC believes the proposal to make technical changes to the Rules would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to this proposed rule change have not been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NSCC–2021–009 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2021–009. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2021–009 and should be submitted on or before August 13, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–15654 Filed 7–22–21; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

[License No. 09/49–0469]

Grayhawk Venture Fund II, L.P.; Surrender of License of Small Business Investment Company

Pursuant to the authority granted to the United States Small Business Administration under the Small Business Investment Act of 1958, as amended, under Section 309 of the Act and Section 107.1900 of the Small Business Administration Rules and Regulations (13 CFR 107.1900) to function as a small business investment company under the Small Business Investment Company License No. 09/49–0469 issued to Grayhawk Venture

[27] *Id.*

[28] *See* note 6, at 76922.

[29] 15 U.S.C. 78q–1(b)(3)(F).

[30] *See* note 6, at 76922.

[31] 17 CFR 200.30–3(a)(12).

Fund II, L.P., said license is hereby declared null and void.

United States Small Business Administration.

Thomas G. Morris,

Acting Associate Administrator, Director, Office of SBIC Liquidation, Office of Investment and Innovation.

[FR Doc. 2021–15665 Filed 7–22–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2021–0167]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Rotorcraft External Load Operator Certificate Application

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

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 26, 2021. The collection involves the submission of FAA Form 8710–4 for the certification process of rotorcraft external-load operators. The information to be collected is necessary to evaluate the applicants' qualifications for certification.

DATES: Written comments should be submitted by August 23, 2021.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the attention of the Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov,* or faxed to (202) 395–6974, or mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Raymond Plessinger by email at: *raymond.plessinger@faa.gov;* phone: 717–443–7296.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0044.

Title: Rotorcraft External Load Operator Certificate Application.

Form Numbers: FAA Form 8710–4.

Type of Review: Renewal.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on February 26, 2021 (86 FR 11821). This collection involves the application for issuance or renewal of a 14 CFR part 133 Rotorcraft External Load Operator Certificate. Application for an original certificate or renewal of a certificate issued under 14 CFR part 133 is made on a form, and in a manner prescribed by the Administrator. The FAA form 8710–4 may be obtained from an FAA Flight Standards District Office, or online at *https://www.faa.gov/documentLibrary/media/form/faa8710-4.pdf.* The completed application is sent to the district office that has jurisdiction over the area in which the applicant's home base of operation is located.

The information collected includes: Type of application, Operator's name/DBAs, telephone number, mailing address, physical address of the principal base of operations, chief pilot/designee name, airman certificate grade and number, rotorcraft make/model registration numbers to be used and load combinations requested. In addition, this information collection includes requirements to report emergency operations, plans for operation over congested areas, and submission of flight manuals for approval, and recordkeeping requirements for certificates and crewmember testing and training records.

Respondents: 357 active part 133 certificate-holders.

Frequency: New applications when needed; current 14 CFR part 133 certificate-holders must renew every 24 months. Flight manuals are submitted as part of the application process, and plans for operation over congested areas are submitted as needed.

Estimated Average Burden per Response (by Section): Section 133.15, Application for Certificate Issuance or Renewal: 0.5 hours; Section 133.21, Personnel: 0.3 hours; Section 133.25, Amendment of Certificate: 0.5 hours; Section 133.27, Availability, transfer, and surrender of certificate: 0.5 hours; Section 133.31, Emergency Operations: 2 hours; Section 133.33, Operating Rules: 2 hours; Section 133.37, Crewmember training, currency, and testing requirements: 0.3 hours; Section 133.47, Rotorcraft Load Combination Flight Manual: 40 hours.

Estimated Total Annual Burden: 3,295 total hours per year, or 9.3 hours per respondent.

Issued in Washington, DC, on July 20, 2021.

Dwayne C. Morris,

Project Manager, Flight Standards Service, General Aviation and Commercial Division.

[FR Doc. 2021–15698 Filed 7–22–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Airport Property at the Roswell Air Center, Roswell, New Mexico

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the release of land at the Roswell Air Center under the provisions of Section 125 of the Wendell H. Ford Aviation Investment Reform Act for the 21st Century (AIR 21).

DATES: Comments must be received on or before August 23, 2021.

ADDRESSES: Comments on this application may be mailed or delivered to the FAA at the following address: Mr. Lacey D. Spriggs, Manager, Federal Aviation Administration, Southwest Region, Airports Division, Louisiana/New Mexico Airports Development Office, ASW–640, Fort Worth, Texas 76177.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Scott Stark, Airport Director, at the following address: 1 Jerry Smith Circle, Roswell, NM 88203.

FOR FURTHER INFORMATION CONTACT: Mr. Jean Gamarra, Program Manager, Federal Aviation Administration,

Louisiana/New Mexico Airports Development Office, ASW–640, 10101 Hillwood Parkway, Fort Worth, Texas 76177, Telephone: (817) 222–5522, Email: *jean.gamarra@faa.gov,* Fax: (817) 222–5989.

SUPPLEMENTARY INFORMATION: The FAA invites public comment on the request to release property at the Roswell Air Center under the provisions of the AIR 21.

The following is a brief overview of the request:

The City of Roswell requests the release of 13.3974 acres of non-aeronautical airport property. The land was acquired by Deed without Warranty from the United States on January 24th, 1968. The property to be released will be sold to allow for future airport development.

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the application, notice and other documents relevant to the application in person at the City of Roswell Legal Department, telephone number (575) 347–5703.

Issued in Fort Worth, Texas, on July 16, 2021.

Ignacio Flores,

Director, Office of Airports Southwest Region.

[FR Doc. 2021–15644 Filed 7–22–21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Availability of Record of Decision for the Environmental Impact Statement (EIS) for the Proposed LaGuardia Access Improvement Project at LaGuardia Airport (LGA), New York City, Queens County, New York

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

ACTION: Notice of availability for Record of Decision.

SUMMARY: This notice is intended to advise the public that on July 20, 2021, the FAA issued a Record of Decision (ROD) for the federal actions reviewed in the Final Environmental Impact Statement (EIS) for the proposed LaGuardia Airport (LGA) Access Improvement Project and its connected actions (the Proposed Action). The ROD includes numerous environmental findings by the FAA, as well as environmental determinations related to funding opportunities that are subject to federal oversight.

The Final EIS and ROD are available for download on the project website at *https://www.lgaaccesseis.com.*

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Brooks, Environmental Program Manager, Eastern Regional Office, AEA–610, Federal Aviation Administration, 1 Aviation Plaza, Jamaica, NY 11434. Telephone: 718–553–2511.

SUPPLEMENTARY INFORMATION: The FAA, as lead agency, has completed and is publishing a ROD for proposed improvements identified at LGA. The ROD was prepared pursuant to Title 40 Code of Federal Regulations (CFR) 1505.2.

The Final EIS for the proposed LGA Access Improvement Project was published on the project website at *www.lgaaccesseis.com* on March 15, 2021 and two Notices of Availability in the **Federal Register** were published; the first by the FAA on March 18, 2021 (86 FR 14796) and the second by the Environmental Protection Agency on March 19, 2021 (86 FR 14908). The FAA prepared the Final EIS pursuant to: The National Environmental Policy Act (NEPA) of 1969, 42 United States Code (U.S.C.) 4321 *et seq.;* the Council of Environmental Quality implementing regulations, 40 CFR parts 1500–1508; FAA Order 1050.1F; and FAA Order 5050.4B. FAA assessed the potential environmental impacts of the Proposed Action, as well as the No Action Alternative.

In the Final EIS, the FAA identified the Proposed Action as its preferred alternative in meeting the purpose and need of addressing unpredictable and increasing travel times to and from LGA and space constraints for employee parking. The Proposed Action includes:

- Construction of an above ground fixed guideway automated people mover (APM) system approximately 2.3 miles in length that extends from the LGA Central Hall Building under construction to the Mets-Willets Point Long Island Rail Road (LIRR) and New York City Transit Subway Flushing Line (7 Line) Stations;
- construction of two on-Airport APM stations (Central Hall APM Station and East APM Station) and one off-Airport APM station at Willets Point (Willets Point APM Station) that provides connections to the Mets-Willets Point LIRR and 7 Line stations;
- construction of passenger walkway systems to connect the APM stations to the passenger terminals, parking garages, and ground transportation facilities;
- construction of a multi-level APM operations, maintenance, and storage facility (OMSF) that includes up to 1,000 parking spaces (500 for airport employees, 250 for Metropolitan Transportation Authority (MTA) employees, 50 for APM employees, and 200 for replacement Citi Field parking);
- construction of three traction power substations to provide power to the APM guideway: One located at the on-Airport East Station, another at-grade west of the proposed Willets Point Station just south of Roosevelt Avenue, and the third at the OMSF;
- construction of a 27kV main substation located adjacent to the OMSF structure on MTA property;
- construction of utilities infrastructure, both new and modified, as needed, to support the Proposed Action, including a permanent stormwater outfall into Flushing Creek and a temporary stormwater outfall into Flushing Creek; and
- acquisition of temporary and permanent easements; no private property will be acquired.

The Proposed Action also includes various connected actions, including: Utility relocation and demolition of certain existing facilities; a temporary MTA bus storage/parking facility; relocation of up to 200 Citi Field parking spaces; demolition and replacement of the Passerelle Bridge; temporary walkway to maintain access between the transit stations and Flushing Meadows-Corona Park; modifications to the Mets-Willets Point LIRR Station, including new shuttle service on the LIRR Port Washington Line; and the relocation of several World's Fair Marina facilities, including a boat lift, finger piers and connected timber floating dock, Marina office and boatyard facility, boat storage and parking, and operations shed.

The ROD includes FAA's favorable environmental findings and determinations needed for the Port Authority to pursue future funding subject to FAA oversight pursuant to 49 U.S.C. 47106 and 47107 and 49 U.S.C. 40117. The findings included in the ROD are:

- The Proposed Action will conform with the Clean Air Act of 1970, as amended (42 U.S.C. 7401 *et seq.*);
- The Proposed Action includes all practicable measures to minimize harm to endangered species as much as such harm may result from implementation of the Proposed Action (Endangered Species Act of 1974, U.S.C. 1531, as amended);
- There is no prudent and feasible alternative to use of lands containing publicly owned parks, recreation areas, national wildlife refuges, or significant historic sites protected under Section

4(f) of the DOT Act, and the Proposed Action includes all possible planning to minimize harm to resources protected under Section 4(f) of the DOT Act (49 U.S.C. 303(c) and Section 106, National Historic Preservation Act);

- Relocation assistance, if any, will be provided in accordance with 42 U.S.C. 460, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970;
- Further mitigation measures or alternatives that would avoid or reduce the disproportionately high and adverse effects to minority environmental justice populations are not practicable (DOT Order 5610.2B and E.O. 12989);
- The Proposed Action would conform to all applicable state and/or local floodplain protection standards (E.O. 11988);
- The Proposed Action complies with the enforceable policies of New York State's approved coastal management program and will be conducted in a manner consistent with such program;
- The Proposed Action conforms to the Avoidance, Minimization and/or Compensation of Harm to Wetlands in Accordance with E.O. 11990 and the Clean Water Act;
- The Proposed Action includes all practicable means to avoid or minimize harm from the alternative selected (40 CFR 1505.2(a)(3)); and
- The FAA has given this proposal the independent and objective evaluation required by the CEQ (40 CFR 1506.5).

The determinations included in the ROD are:

- The Proposed Action is reasonably consistent with existing plans of public agencies for development of areas surrounding the airport (49 U.S.C. 47106(a)(1)), and E.O. 12372;
- Appropriate action, including the adoption of zoning laws, has been or will be taken as reasonable to restrict the land use next to or near the airport to uses that are compatible with airport operations (49 U.S.C. 47107(a)(10)); and
- The interest of the communities in or near where the Proposed Action may be located were given fair consideration (49 U.S.C. 47106(b)(2)).

This ROD also presents the decision of the NPS, as cooperating agency in the Final EIS, to approve a partial conversion of 0.5 acres of parklands subject to the Land and Water Conservation Fund (LWCF) Act in Flushing Meadows-Corona Park, as well as to approve a Temporary Non-Conforming Use (TNCU) of 1.2 acres of parkland subject to the LWCF Act.

A copy of the ROD is available for public review at FAA's website: *https://www.faa.gov/airports/environmental/records_decision;* and the LGA Access Improvement Project EIS website: *http://www.LGAaccessEIS.com.*

Issued in Jamaica, New York, July 20, 2021.

Patricia Henn,

Manager, Planning and Programming Branch, Airports Division, Eastern Region.

[FR Doc. 2021–15704 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions of Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on Claims for Judicial Review of Actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final within the meaning of the regulation. The actions relate to a proposed highway project on State Route 198 from post mile R11.3/R12.0 and on State Route 216 from post mile R0.0/R2.56 in Tulare County for the Lovers Lane Operational Improvements and Rehabilitation Project. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 20, 2021. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Richard Putler, Senior Environmental Planner, Caltrans, 2015 East Shields Avenue, Suite 200, Fresno, CA 93721; phone number 559–304–6599, *richard.putler@dot.ca.gov.* For FHWA, contact David Tedrick at (916) 498–5024 or email *david.tedrick@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, FHWA assigned, and Caltrans assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Caltrans proposes making operational improvements at the Lovers Lane Undercrossing (Tulare-198-Post Mile 11.7, Bridge Number 46–216) and restoring the existing facility to a state of good repair. The project covers a 0.7-mile segment of State Route 198 from 0.3 mile west of the Lovers Lane Undercrossing to 0.5 mile east of it. The operational improvements consist of widening Lovers Lane below the undercrossing and improving the following four intersections: Lovers Lane (State Route 216) at Mineral King Avenue, Lovers Lane at State Route 198 on the eastbound on-ramps and off-ramps, Lovers Lane at Noble Avenue, and State Route 198 on the westbound on-ramps and off-ramps at Mineral King Avenue. The project also proposes to extend the life of the existing pavement along State Route 216 by rehabilitating the existing pavement and including all pertinent standards as required by the 3R Program (resurfacing, restoration, and rehabilitation).

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (EA) for the project, approved on June 23th 2021, in the Finding of No Significant Impact (FONSI) issued on June 23th 2021, and in other documents in the FHWA project records. The EA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans EA and FONSI can be obtained by contacting Caltrans: Richard Putler, Senior Environmental Planner, Caltrans, 2015 East Shields Avenue, Suite 200, Fresno, CA 93721; phone number 559–304–6599, *richard.putler@dot.ca.gov,* or viewed at public libraries in the project area. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. Council on Environmental Quality regulations (40 CFR 1500 *et seq.;* 23 CFR 771);
2. National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4351 *et seq.*);
3. Moving Ahead for Progress in the 21st Century Act (Map-21, Pub. L. 112–141);
4. Noise Control Act of 1979 (42 U.S.C. 4901 *et seq.*);
3. Clean Air Act of 1963, as amended (42 U.S.C. 7401 *et seq.*);
4. Farmland Protection Policy Act (7 U.S. Code 4201–4209);
5. Department of Transportation Act of 1966, Section 4(f) (49 U.S.C. 303);
6. Migratory Bird Treaty Act (16 U.S.C. 703–712);

7. National Historic Preservation Act of 1966, as amended (54 U.S.C. 306108 *et seq.*);

8. Federal Highway Act of 1970 (23 U.S.C. 109);

9. FHWA Noise Standards, Policies, and Procedures (23 CFR 772);

10. Endangered Species Act of 1973 (16 U.S.C. 1531–1543);

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: July 19, 2021.

Rodney Whitfield,

Director, Financial Services, Federal Highway Administration, California Division.

[FR Doc. 2021–15705 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0036]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of denial.

SUMMARY: FMCSA announces its decision to deny the application from one individual treated with an Implantable Cardioverter Defibrillator (ICD) who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2021–0036, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.transportation.gov/privacy.*

II. Background

On February 9, 2021, FMCSA published a **Federal Register** notice (86 FR 8830) announcing receipt of an application from one individual treated with an ICD and requested comments from the public. The individual requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period closed on March 11, 2021, and one comment was received.

FMCSA has evaluated the eligibility of the applicant and concluded that granting an exemption would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(4). A summary of the applicant's medical history related to the ICD exemption request was discussed in the February 9, 2021, **Federal Register** notice and will not be repeated here.

The Agency's decision regarding this exemption application is based on information from the Cardiovascular Medical Advisory Criteria, an April 2007 evidence report titled ''Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,'' [1] and a December 2014 focused research report titled ''Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed.'' Copies of these reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.[2] The advisory criteria for § 391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. ICDs are disqualifying due to risk of syncope.

III. Discussion of Comments

FMCSA received one comment in this proceeding. The comment was from a private citizen who did not support granting the exemption. The individual disagreed that granting an exemption for an ICD would ensure the safety of the driver and local pedestrians.

FMCSA evaluates each ICD application received to determine whether an equivalent or greater level of safety can be achieved by the applicant. While FMCSA has received and carefully evaluated many ICD exemption application requests, thus far the Agency has been unable to conclude that granting an exemption to any of the applicants would achieve a level of safety equivalent to, or greater than, the level of safety maintained without an exemption.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding this exemption application is based on an

[1] The report is available on the internet at *https://rosap.ntl.bts.gov/view/dot/16462.*

[2] These criteria may be found in 49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section D. *Cardiovascular: § 391.41(b)(4),* paragraph 4, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

individualized assessment of the applicant's medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report referenced previously upholds the findings of the April 2007 report and indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety.

IV. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting this exemption would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following applicant has been denied an exemption from the physical qualification standards in § 391.41(b)(4):

Matthew Wackt (WI)

The applicant has, prior to this notice, received a letter of final disposition regarding his exemption request. The decision letter fully outlined the basis for the denial and constitute final action by the Agency. The name of the individual published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2021–15739 Filed 7–22–21; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Requirements; Information Collection Renewal; Submission for OMB Review; Release of Non-Public OCC Information

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA). In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Release of Non-Public OCC Information.'' The OCC also is giving notice that it has submitted the collection to OMB for review.

DATES: You should submit written comments by August 23, 2021.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0200, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0200'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

You may review comments and other related materials that pertain to this information collection [1] following the close of the 30-day comment period for this notice by the following method:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0200'' or ''Release of Non-Public Information.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection in this document.

Title: Release of Non-Public OCC Information.

OMB Control No.: 1557–0200.

Abstract: The information collection requirements require individuals who are requesting non-public OCC information to provide the OCC with information regarding the legal grounds for the request. The release of non-public OCC information to a requester without sufficient legal grounds to obtain the information would inhibit open consultation between a bank and the OCC, thereby impairing the OCC's supervisory and regulatory mission. The OCC is entitled, under statute and case law, to require requesters to demonstrate that they have sufficient legal grounds for the OCC to release non-public OCC information. The OCC needs to identify the requester's legal grounds to determine if it should release the requested non-public OCC information.

The information requirements in 12 CFR part 4, subpart C, are as follows:

[1] On April 8, 2021, the OCC published a 60-day notice for this information collection, 86 FR 18371.

• 12 CFR 4.33: Request for non-public OCC records or testimony;

• 12 CFR 4.35(b)(3): Third parties requesting testimony;

• 12 CFR 4.37(a)(2): OCC former employee notifying OCC of subpoena;

• 12 CFR 4.37(a) and (b): Prohibition on dissemination of released information;

• 12 CFR 4.38(a) and (b): Restrictions on dissemination of released information; and

• 12 CFR 4.39(d): Request for authenticated records or certificate of nonexistence of records.

The OCC uses the information to process requests for non-public OCC information and to determine if sufficient grounds exist for the OCC to release the requested information or provide testimony that would include a discussion of non-public information. This information collection facilitates the processing of requests and expedites the OCC's release of non-public information and testimony to the requester, as appropriate.

Type of Review: Extension, without change, of a currently approved collection.

Affected Public: Businesses or other for-profit; individuals.

Number of Respondents: 2.

Frequency of Response: On occasion.

Total Annual Burden: 6 hours.

On April 8, 2021, the OCC published a 60-day notice for this information collection, 86 FR 18371. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(b) The accuracy of the agency's estimate of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2021–15659 Filed 7–22–21; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 2210 and 2210–F

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 2210, Underpayment of Estimated Tax by Individuals, Estate, and Trusts, and Form 2210–F, Underpayment of Estimated Tax by Farmers and Fishermen.

DATES: Written comments should be received on or before September 21, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to Sara Covington at Internal Revenue Service, (737) 800–6149, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Underpayment of Estimated Tax by Individuals, Estate, and Trusts (Form 2210), and Underpayment of Estimated Tax by Farmers and Fishermen (Form 2210–F).

OMB Number: 1545–0140.

Form Number: 2210 AND 2210–F.

Abstract: Internal Revenue Code section 6654 imposes a penalty for failure to pay estimated tax. Form 2210 is used by individuals, estates, and trusts. Form 2210–F is used by farmers and fisherman to determine whether they are subject to the penalty and to compute the penalty if it applies. The Service uses this information to determine whether taxpayers are subject to the penalty, and to verify the penalty amount. If you're self-employed, the Coronavirus Aid, Relief and Economic Security (CARES) Act allows you to defer the deposit or payment of 50% of the social security tax on net earnings from self-employment imposed on March 27, 2020, through December 31, 2020.

Current Actions: There are no changes to the forms at this time; the burden hours are reduced based on the most current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, and farms.

Estimated Number of Respondents: 80,150.

Estimated Time per Respondent: 4 hrs.

Estimated Total Annual Burden Hours: 312,897.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 20, 2021.

Sara L. Covington,

IRS, Tax Analyst.

[FR Doc. 2021–15766 Filed 7–22–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

List of Countries Requiring Cooperation With an International Boycott

In accordance with section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

Iraq
Kuwait
Lebanon
Libya
Qatar
Saudi Arabia
Syria
Yemen

Kevin Nichols,

International Tax Counsel (Tax Policy).

[FR Doc. 2021–15675 Filed 7–22–21; 8:45 am]

BILLING CODE 4810–AK–P



FEDERAL REGISTER

Vol. 86 Friday,

No. 139 July 23, 2021

Book 2 of 2 Books

Pages 39103–39938

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, et al.

Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 405, 410, 411, 414, 415, 423, 424, and 425

[CMS–1751–P]

RIN 0938–AU42

Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and post-payment medical review activities; requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan, or a Medicare Advantage Prescription Drug (MA–PD) plan; updates to the Medicare Ground Ambulance Data Collection System; changes to the Medicare Diabetes Prevention Program (MDPP) expanded model; and amendments to the physician self-referral law regulations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 13, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1751–P. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1751–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1751–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

DivisionofPractitionerServices@cms.hhs.gov, for any issues not identified below.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Donta Henson, (410) 786–1947, Patrick Sartini, (410) 786–9252, and Larry Chan, (410) 786–6864, for issues related to telehealth services and other services involving communications technology.

Julie Adams, (410) 786–8932, for issues related to payment for anesthesia services.

Sarah Leipnik, (410) 786–3933, for issues related to split (or shared) services.

Christiane LaBonte, (410) 786–7237, for issues related to indirect practice expense, PFS payment for critical care services, and PFS payment for teaching physician services.

DivisionofPractitionerServices@cms.hhs.gov, for issues related to payment for vaccine administration services.

Regina Walker-Wren, (410) 786–9160, for issues related to billing for services of physician assistants.

Pamela West, (410) 786–2302, for issues related to PFS payment for therapy services, medical nutrition therapy services, and services of registered dieticians and nutrition professionals.

Liane Grayson, (410) 786–6583, and Donta Henson, (410) 786–1947, for issues related to coinsurance for certain colorectal cancer screening services.

Lisa Parker, (410) 786–4949, for issues related to RHCs and FQHCs.

Laura Kennedy, (410) 786–3377, for issues related to drugs payable under Part B.

Heather Hostetler, (410) 786–4515, and Elizabeth Truong, 410–786–6005, for issues related to removal of select national coverage determinations.

Sarah Fulton, (410) 786–2749, for issues related to Appropriate Use Criteria for Advanced Diagnostic Imaging (AUC); and Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation.

Rachel Katonak, (410) 786–8564, for issues related to Medical Nutrition Therapy.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment, repayment mechanism requirements, and benchmarking methodology.

Naseem Tarmohamed, (410) 786–0814, or *SharedSavingsProgram@cms.hhs.gov,* for inquiries related to Shared Savings Program application, compliance and beneficiary notification requirements.

Amy Gruber, *AmbulanceDataCollection@cms.hhs.gov,* for issues related to the Medicare Ground Ambulance Data Collection System.

Juliana Tiongson, (410) 786–0342, for issues related to the Medicare Diabetes Prevention Program (MDPP).

Laura Ashbaugh, (410) 786–1113, for issues related to Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance and Use of Electronic Travel Logs.

Frank Whelan, (410) 786–1302, for issues related to Medicare provider enrollment regulation updates.

Thomas J. Kessler, (410) 786–1991, for issues related to provider and supplier prepayment and post-payment medical review requirements.

Lindsey Baldwin, (410) 786–1694, and Michele Franklin, (410) 786–9226, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Lisa O. Wilson, (410) 786–8852, or Meredith Larson, (410) 786–7923, for inquiries related to the physician self-referral law.

Joella Roland, (410) 786–7638, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan.

Kathleen Ott, (410) 786–4246, for issues related to open payments.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Brittany LaCouture, (410) 786–0481, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website: The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.* Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2022 PFS proposed rule, refer to item CMS–1751–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *DivisionofPractitionerServices@cms.hhs.gov.*

CPT (Current Procedural Terminology) Copyright Notice: Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

This major proposed rule proposes to revise payment polices under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this major proposed rule includes proposals regarding other Medicare payment policies described in sections III. and IV.

A. Summary of the Major Provisions

The statute requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that we establish each year by regulation the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing to establish RVUs for CY 2022 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this proposed rule addresses:

- Practice Expense RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Telehealth and Other Services Involving Communications Technology (section II.D.)
- Valuation of Specific Codes (section II.E.)
- Evaluation and Management Visits (section II.F.)
- Billing for Physician Assistant Services (section II.G.)
- Therapy Services (section II.H.)
- Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests (section II.I.)
- Vaccine Administration Services (section II.J.)
- Payment for Medical Nutrition Therapy Services and Related Services (section II.K.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (sections III.A., III.B., and III.C.)
- Requiring Certain Manufacturers to Report Drug Pricing Information for Part B and Determination of ASP for Certain Self-administered Drug Products (sections III.D.1. and 2.)
- Medicare Part B Drug Payment for Drugs Approved under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act (section III.E.)
- Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.F.)
- Removal of Select National Coverage Determinations (section III.G.)
- Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (section III.H.)
- Medical Nutrition Therapy (section III.I.)
- Medicare Shared Savings Program (section III.J.)
- Medicare Ground Ambulance Data Collection System (section III.K.)
- Medicare Diabetes Prevention Program (MDPP) (section III.L.)
- Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs (section III.M.)
- Medicare Provider and Supplier Enrollment Changes (section III.N.1.)
- Provider/Supplier Medical Review Requirements: Addition of Provider/Supplier Requirements related to Prepayment and Post-payment Reviews (section III.N.2.)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.O.)
- Updates to the Physician Self-Referral Regulations (section III.P.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) (section III.Q.)
- Open Payments (section III.R.)
- Updates to the Quality Payment Program (section IV.)
- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

3. Summary of Costs and Benefits

We have determined that this proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

II. Provisions of the Proposed Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, October 31, 1994), amended by section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (BBA '97) (Pub. L. 105–33, August 5, 1997) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA '97 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113, November 29, 1999) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with

comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA '97 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently from one another. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VII. of this proposed rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we will make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2020 PFS final rule for a discussion of the last GPCI update (84 FR 62615 through 62623).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS' Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

$$\text{Payment} = [(\text{RVU work} \times \text{GPCI work}) + (\text{RVU PE} \times \text{GPCI PE}) + (\text{RVU MP} \times \text{GPCI MP})] \times \text{CF}$$

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty,

nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2022 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

For CY 2022, we have incorporated the available utilization data for two new specialties, each of which became a recognized Medicare specialty during 2020. These specialties are Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD). We are proposing to use proxy PE/HR values for these new specialties, as there are no PPIS data for these specialties, by crosswalking the PE/HR as follows from specialties that furnish similar services in the Medicare claims data:

- Micrographic Dermatologic Surgery (MDS) from Dermatology; and
- Adult Congenital Heart Disease (ACHD from Cardiology.

These updates are reflected in the ''CY 2022 PFS proposed rule PE/HR'' file available on the CMS website under the supporting data files for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00,

the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.

- Then, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect

allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(**Note:** For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (**Note:** For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

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TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- Crosswalk *certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical *therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (*Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only*), is associated with the global service, CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%
CO, CQ	Physical and Occupational Therapy Assistant Services	88%	88%

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We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

Beginning in CY 2022, section 1834(v)(1) of the Act requires that we apply a 15 percent payment reduction for outpatient occupational therapy services and outpatient physical therapy services that are provided, in whole or in part, by a physical therapist assistant (PTA) or occupational therapy assistant (OTA). Section 1834(v)(2)(A) of the Act required CMS to establish modifiers to identify these services, which we did in the CY 2019 PFS final rule (83 FR 59654 through 59661), creating the CQ and CO payment modifiers for services provided in whole or in part by PTAs and OTAs, respectively. These payment modifiers are required to be used on claims for services with dates of service beginning January 1, 2020, as specified in the CY 2020 PFS final rule (84 FR 62702 through 62708). We will apply the 15 percent payment reduction to therapy services provided by PTAs (using the CQ modifier) or OTAs (using the CO modifier), as required by statute. Under sections 1834(k) and 1848 of the Act, payment is made for outpatient therapy services at 80 percent of the lesser of the actual charge or applicable fee schedule amount (the allowed charge). The remaining 20 percent is the beneficiary copayment. For therapy services to which the new discount applies, payment will be made at 85 percent of the 80 percent of allowed charges. Therefore, the volume discount factor for therapy services to which the CQ and CO modifiers apply is: (0.20 + (0.80* 0.85), which equals 88 percent.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work *RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 − (1/((1 + interest rate)^ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.
usage = variable, see discussion below in this proposed rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.
- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 3.

TABLE 3: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2022.

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2022 direct PE input public use files, which are available on the CMS website under downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised

codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases, the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2022, we are continuing to display two versions of the Labor Task Detail public use file: one version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Technical Corrections to Direct PE Input Database and Supporting Files

For CY 2022, we are proposing to address the following:

- Following the publication of the CY 2021 PFS proposed rule, several commenters questioned the proposed RVUs associated with several occupational therapy evaluation procedures (CPT codes 97165 through 97167). Commenters stated that the PE valuation for these codes appeared to be illogical as it was counterintuitive for the PE RVU to go down as the level of complexity increased. Commenters stated that the distribution of code usage has not changed in any manner to justify a reduction in the code values and that all three evaluation codes should reimburse at the same rate. In response to the commenters, we noted that although the three codes in question shared the same work RVU and the same direct PE inputs, they did not share the same specialty distribution in the claims data and therefore would not necessarily receive the same allocation of indirect PE. In the CY 2021 PFS final rule (85 FR 84490), we finalized the implementation of a technical change intended to ensure that these three services received the same allocation of indirect PE. We agreed with commenters that it was important to avoid a potential rank order anomaly in which the simple case for a service was valued higher than the complex case.

After the publication of the CY 2021 PFS final rule, stakeholders stated their appreciation for the technical change made in the final rule to ensure that the indirect PE allocation was the same for all three levels of occupational therapy evaluation codes. However, stakeholders expressed concern that the PE RVUs we finalized for CPT codes

the PE RVUs we proposed for CY 2021. Stakeholders stated that nothing had occurred in the past year that would account for a reduction to the proposed PE for these codes, especially in a year where the proposed PE increased for the corresponding physical therapy evaluation procedures (CPT codes 97161–97163), and stakeholders questioned whether there had been an error in applying the indirect PE methodology.

We reviewed the indirect PE allocation for CPT codes 97165–97167 in response to the stakeholder inquiry and we do not agree that there was an error in applying the indirect PE methodology. We finalized a technical change in the CY 2021 PFS final rule intended to ensure that these three services received the same allocation of indirect PE, which achieved its desired goal of assigning equivalent indirect PE to these three services. However, by forcing CPT codes 97165–97167 to have the same indirect PE allocation, the indirect PE values for these codes no longer relied on the claims data, which ended up affecting the indirect practice cost index for the wider occupational therapy specialty. Because CPT codes 97165–97167 are high volume services, this resulted in a lower indirect practice cost index for the occupational therapy specialty and a smaller allocation of indirect PE for CY 2021 than initially proposed.

We are addressing this issue for CY 2022 by proposing to assign all claims data associated with CPT codes 97165–97167 to the occupational therapy specialty. This should ensure that CPT codes 97165–97167 would always receive the same indirect PE allocation as well as preventing any fluctuations to the indirect practice cost index for the wider occupational therapy specialty. This proposal is intended to avoid a potential rank order anomaly in which the simple case for a service is valued higher than the complex case. As the utilization for CPT codes 97165–97167 is overwhelmingly identified as performed by occupational therapists, we do not anticipate that assigning all of the claims data for these codes to the occupational therapy specialty will have a noticeable effect on their valuation. We are soliciting public comments regarding this proposal, and specifically on what commenters suggest as the most appropriate method of assigning indirect PE allocation for these services.

- In the CY 2020 PFS final rule (84 FR 63102 through 63104), we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis for the provision of self-administered esketamine. In the CY 2021 PFS final rule, we finalized a proposal to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that summed the values associated with several codes (85 FR 84641 through 84642). Following the publication of the CY 2021 PFS final rule, stakeholders expressed their concern that the finalized PE RVU had decreased for HCPCS codes G2082 and G2083 as compared to the proposed valuation and as compared to the previous CY 2020 interim final valuation. Stakeholders questioned whether there had been an error in the PE allocation since CMS had finalized increases in the direct PE inputs for the services.

We reviewed the indirect PE allocation for HCPCS codes G2082 and G2083 in response to the stakeholder inquiry and discovered a technical change that was applied in error. Specifically, we inadvertently assigned a different physician specialty than we intended (''All Physicians'') to HCPCS codes G2082 and G2083 for indirect PE allocation in our ratesetting process during valuation of these codes in the CY 2020 PFS final rule, and continued that assignment into the CY 2021 PFS proposed rule. This specialty assignment caused the PE value for these services to be higher than anticipated for CY 2020. We intended to revise the assigned physician specialty for these codes to ''General Practice'' in the CY 2021 PFS final rule; however, we neglected to discuss this change in the course of PFS rulemaking for CY 2021. Since we initially applied this technical change in the CY 2021 PFS final rule without providing an explanation, we issued a correction notice (86 FR 14690) to remove this change from the CY 2021 PFS final rule, and to instead maintain the All Physicians specialty assignment through CY 2021. We apologize for any confusion this may have caused.

For CY 2022, we are proposing to maintain the currently assigned physician specialty for indirect PE allocation for HCPCS codes G2082 and G2083. We are proposing to assign these two services to the All Physicians specialty for indirect PE allocation which will maintain payment consistency with the rates published in the CY 2020 PFS final rule and the CY 2021 PFS proposed rule. Although we had previously intended to assign the General Practice specialty to these codes, stakeholders have provided additional information about these services suggesting that maintaining the All Physicians specialty assignment for these codes will help maintain payment stability and preserve access to this care for beneficiaries. We are soliciting public comments to help us discern which specialty would be the most appropriate to use for indirect PE allocation for HCPCS codes G2082 and G2083. We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, should appropriately reflect the typical costs for the specialty the commenters suggest. For example, we do not believe it would be appropriate to assign the Psychiatry specialty for these services given that HCPCS codes G2082 and G2083 include the high direct costs associated with esketamine supplies. The Psychiatry specialty is an outlier compared to most other specialties, allocating indirect costs at a 15:1 ratio based on direct costs because psychiatry services typically have very low direct costs. Assignment of most other specialties would result in allocation of direct costs at roughly a 3:1 ratio. We request that commenters explain in their comments how the indirect PE allocation would affect the payment for these services. Specifically, to ensure appropriate payment for HCPCS codes G2082 and G2083, we would like to get a better understanding of the indirect costs associated with these services, relative to other services furnished by the suggested specialty.

- A stakeholder contacted us regarding a potential error involving the intraservice work time for CPT code 35860 (*Exploration for postoperative hemorrhage, thrombosis or infection; extremity*). The stakeholder stated that the RUC recommended an intraservice work time of 90 minutes for this code when it was last reviewed in the CY 2012 PFS final rule and we finalized the work time without refinement at 60 minutes (76 FR 73131). The stakeholder requested that the intraservice work time for CPT code 35860 should be updated to 90 minutes.

We reviewed the intraservice work time for CPT code 35860 and found that the RUC inadvertently recommended a time of 60 minutes for the code, which we proposed and finalized without comment in rulemaking for the CY 2012 PFS. As a result, we do not believe that this is a technical error on our part. However, since the stakeholder has clarified that the RUC intended to recommend 90 minutes of intraservice work time for CPT code 35860 based on the surveyed median time, we are proposing to update the intraservice work time to 90 minutes to match the survey results.

c. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2022, we are proposing to update the price of six supplies and two equipment items in response to the public submission of invoices. Since this is the final year of the supply and equipment pricing update, the new pricing for each of these supply and equipment items will take effect for CY 2022 as there are no remaining years of the transition. The six supply and equipment items with proposed updated prices are listed in the valuation of specific codes section of the preamble under Table 16: CY 2022 Invoices Received for Existing Direct PE Inputs.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, April 1, 2014) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- The **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if we were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-

up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 4.

TABLE 4: Example of Direct PE Pricing Transition

Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 difference between $150 and $200
Final (CY 2022) Price	$200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer timeframe will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475 through 59480). In each instance in which a commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479 through 59480).

After consideration of the public comments, we finalized our proposals

associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2022, we received invoice submissions from stakeholders for approximately half a dozen supply and equipment codes as part of the fourth year of the market-based supply and equipment pricing update. We used these submitted invoices in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. We reviewed the invoices, as well as our own data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this review, we are proposing to update the prices of six supply items listed in the valuation of specific codes section of the preamble under Table 16: CY 2022 Invoices Received for Existing Direct PE Inputs. Since this is the final year of the supply and equipment pricing update, the new pricing for each of these supply and equipment items would take effect immediately for CY 2022.

The proposed prices for the supply and equipment items listed in Table 16 of CY 2022 were generally calculated following our standard methodology of averaging together the prices on the submitted invoices. In the case of the Liquid coverslip (Ventana 650–010) (SL479) supply, we are proposing a price of $0.051 based on the median invoice due to the presence of an outlier invoice that substantially increased the pricing when using an average. We believe that the proposed price of $0.051 would be more typical for the SL479 supply based on the pricing information contained on the other submitted invoices. We also received several invoices for the 3C patch system (SD343) supply; however, since we established a price of $625.00 for this supply in last year's CY 2021 PFS final rule and the submitted invoices had an average price of $612.50, we are not proposing to update the price. We believe that the submitted invoices confirm that the current pricing of $625.00 is typical for the SD343 supply.

(2) Invoice Submission

The full list of updated supply and equipment pricing as implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Stakeholders are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

(3) Autologous Platelet-Rich Plasma (HCPCS Code G0460) Supply Inputs

We did not make any proposals associated with HCPCS code G0460 (*Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment*) in the CY 2021 PFS proposed rule. Following publication of the rule, stakeholders contacted CMS regarding the creation of a new 3C patch system supply, which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. Stakeholders first sought clarification on how CMS calculated the underlying nonfacility PE RVUs for HCPCS code G0460. Stakeholders also stated that autologous platelet rich plasma administration procedures furnished in clinical trials (including the new 3C patch system) are reported using HCPCS code G0460 and requested that CMS revalue the service to reflect the PEs associated with the new patch system supply. The stakeholders stated that the use of the new 3C patch system will represent the typical case for HCPCS code G0460, and suggested that, therefore, the cost inputs for this supply should be used to establish the RVUs for this code, as the current PFS payment rate is substantially less than the amount it costs to furnish the 3C patch.

We want to clarify that the direct PE inputs for HCPCS code G0460 increased for CY 2021 as a result of the ongoing market-based supply and equipment pricing update. However, there was also a minor decrease in the indirect PE allocation associated with this service for CY 2021, with the net result that the proposed PE RVU coincidentally ended up remaining the same as in the previous year. We also clarify that HCPCS code G0460 is not included in the Anticipated Specialty Assignment for Low Volume Services list, and therefore, was unaffected by low utilization in the claims data. In addition, as a contractor priced service, HCPCS code G0460 is unaffected by inclusion or exclusion from this list.

We share the concerns of the stakeholders that patient access to the 3C patch could be materially impacted if CMS maintains the current PE RVUs for HCPCS G0460. In the CY 2021 PFS final rule, we established contractor pricing for HCPCS code G0460 for CY 2021. We believe that the use of contractor pricing again for CY 2022 will allow us additional time to consider the most appropriate resource inputs and PE RVUs for HCPCS code G0460. We also added the 3C patch system to our supply database under supply code SD343 at a price of $625.00 based on an average of the submitted invoices. We are proposing to maintain contractor pricing for CY 2022 for HCPCS code G0460 as we do not currently have sufficient information to establish national pricing. It remains unclear to us what the typical supply inputs would be for HCPCS code G0460 and whether they would include the use of the new 3C patch system. We believe that it would be more appropriate to maintain contractor pricing for the service, which will allow for more flexibility in pricing. We are soliciting any additional information that commenters can supply that CMS should consider to establish national payment for HCPCS code G0460.

d. Clinical Labor Pricing Update

Section 220(a) of the PAMA provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and

that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

Since 2019, we have been updating the supply and equipment prices used for PE as part of a market-based pricing transition; CY 2022 will be the final year of this 4-year transition. We initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the supply and equipment pricing for CY 2019, and we finalized a policy in CY 2019 to phase in the new pricing over a period of 4 years. However, we did not propose to update the clinical labor pricing, and the pricing for clinical labor has remained unchanged during this pricing transition. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available; we refer readers to the full discussion in the CY 2002 PFS final rule for additional details (66 FR 55257 through 55262).

Stakeholders have raised concerns that the long delay since clinical labor pricing was last updated has created a significant disparity between CMS' clinical wage data and the market average for clinical labor. In recent years, a number of stakeholders have suggested that certain wage rates are inadequate because they do not reflect current labor rate information. Some stakeholders have also stated that updating the supply and equipment pricing without updating the clinical labor pricing could create distortions in the allocation of direct PE. Since the pool of aggregated direct PE inputs is budget neutral, if these rates are not routinely updated, clinical labor may become undervalued over time relative to equipment and supplies, especially since the supply and equipment prices are in the process of being updated. There has been considerable stakeholder interest in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), stakeholders supported the idea.

Therefore, we are proposing to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update. We believe it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We are proposing to use the methodology outlined in the CY 2002 PFS final rule (66 FR 55257), which draws primarily from BLS wage data, to calculate updated clinical labor pricing. As we stated in the CY 2002 PFS final rule, the BLS' reputation for publishing valid estimates that are nationally representative led to the choice to use the BLS data as the main source. We believe that the BLS wage data continues to be the most accurate source to use as a basis for clinical labor pricing and this data will appropriately reflect changes in clinical labor resource inputs for purposes of setting PE RVUs under the PFS. We used the most current BLS survey data (2019) as the main source of wage data for this proposal.

We recognize that the BLS survey of wage data does not cover all the staff types contained in our direct PE database. Therefore, we crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible. In situations where the price wages of clinical labor types were not referenced in the BLS data, we have used the national salary data from the Salary Expert, an online project of the Economic Research Institute that surveys national and local salary ranges and averages for thousands of job titles using mainly government sources. (A detailed explanation of the methodology used by Salary Expert to estimate specific job salaries can be found at *www.salaryexpert.com*). We previously used Salary Expert information as the primary backup source of wage data during the last update of clinical labor pricing in CY 2002. If we did not have direct BLS wage data available for a clinical labor type, we used the wage data from Salary Expert as a reference for pricing, then crosswalked these clinical labor types to a proxy BLS labor category rate that most closely matched the reference wage data, similar to the crosswalks used in our PE/HR allocation. For example, there is no direct BLS wage data for the Mammography Technologist (L043) clinical labor type; we used the wage data from Salary Expert as a reference and identified the BLS wage data for Respiratory Therapists as the best proxy category. We calculated rates for the ''blend'' clinical labor categories by combining the rates for each labor type in the blend and then dividing by the total number of labor types in the blend.

As in the CY 2002 clinical labor pricing update, the proposed cost per minute for each clinical staff type was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type, the proposed cost per minute for the clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the hourly wage rate and then again by 60 to arrive at the per minute cost. To account for the employers' cost of providing fringe benefits, such as sick leave, we used the same benefits multiplier of 1.366 as employed in CY 2002. As an example of this process, for the Physical Therapy Aide (L023A) clinical labor type, the BLS data reflected an average hourly wage rate of $14.03, which we multiplied by the 1.366 benefits modifier and then divided by 60 minutes to arrive at the proposed per-minute rate of $0.32.

Table 5 lists our proposed updates to the clinical labor prices. The BLS occupational code used as a source of wage data is listed for each clinical labor type; for the ''blend'' clinical labor types, this may include multiple BLS occupational codes and other clinical labor types which were calculated separately and then averaged together. Clinical labor types without a direct BLS labor category where we are employing a proxy BLS wage rate are indicated with an asterisk in Table 5.

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TABLE 5: Proposed Clinical Labor Pricing Update

Labor Code	Labor Description	Source	Current Rate Per Minute	Updated Rate Per Minute	% Change
L023A	Physical Therapy Aide	BLS 31-2022	0.23	0.32	39%
L026A	Medical/Technical Assistant	BLS 31-9092	0.26	0.39	50%
L030A	Lab Tech/MTA	L033A, L026A	0.30	0.50	67%
L032B	EEG Technician	BLS 29-2098	0.32	0.51	59%
L033A	Lab Technician	BLS 29-2010	0.33	0.60	82%
L033B	Optician/COMT	BLS 29-2081, BLS 29-2057	0.33	0.44	33%
L035A	Lab Tech/Histotechnologist	L033A, L037B	0.35	0.62	77%
L037A	Electrodiagnostic Technologist	BLS 29-2098	0.37	0.51	38%
L037B	Histotechnologist*	BLS 29-9098	0.37	0.64	73%
L037C	Orthoptist*	BLS 29-1141	0.37	0.85	130%
L037D	RN/LPN/MTA	L051A, BLS 29-2061, L026A	0.37	0.59	59%
L037E	Child Life Specialist*	BLS 21-1023	0.37	0.57	54%
L038A	COMT/COT/RN/CST*	BLS 29-2057, BLS 29-2061, L051A, BLS 19-4010	0.38	0.57	50%
L038B	Cardiovascular Technician*	BLS 31-2011	0.38	0.68	79%
L038C	Medical Photographer*	BLS 29-2050	0.38	0.41	7%
L039A	Certified Retinal Angiographer*	BLS 29-2010	0.39	0.60	54%
L039B	Physical Therapy Assistant	BLS 31-2021	0.39	0.64	64%
L039C	Psychometrist*	BLS 21-1029	0.39	0.68	73%
L041A	Angio Technician*	BLS 29-9000	0.41	0.62	51%
L041B	Radiologic Technologist	BLS 29-2034	0.41	0.69	68%
L041C	Second Radiologic Technologist for Vertebroplasty	BLS 29-2034	0.41	0.69	68%
L042A	RN/LPN	L051A, BLS 29-2061	0.42	0.69	64%
L042B	Respiratory Therapist	BLS 29-1126	0.42	0.70	67%
L043A	Mammography Technologist*	BLS 29-1126	0.43	0.70	63%
L045A	Cytotechnologist*	BLS 29-2035	0.45	0.81	80%
L045B	Electron Microscopy Technologist*	BLS 29-1124	0.45	1.00	122%
L045C	CORF socialworker/psychologist	BLS 21-1022, BLS 19-3031	0.45	0.80	78%
L046A	CT Technologist*	BLS 29-2035	0.46	0.81	76%
L047A	MRI Technologist	BLS 29-2035	0.47	0.81	72%
L047B	REEGT (Electroencephalographic Tech)*	BLS 29-2035	0.47	0.81	72%
L047C	RN/Respiratory Therapist	L051A, L042B	0.47	0.77	64%
L047D	RN/Registered Dietician	L051A, BLS 29-1031	0.47	0.77	64%
L049A	Nuclear Medicine Technologist	BLS 29-2033	0.62	0.88	43%
L050A	Cardiac Sonographer	BLS 29-2032	0.50	0.83	66%
L050B	Diagnostic Medical Sonographer	BLS 29-2032	0.50	0.83	66%
L050C	Radiation Therapist	BLS 29-1124	0.50	1.00	100%
L050D	Second Radiation Therapist for IMRT	BLS 29-1124	0.50	1.00	100%
L051A	RN	BLS 29-1141	0.51	0.85	67%
L051B	RN/Diagnostic Medical Sonographer	L051A, BLS 29-2032	0.51	0.84	65%
L051C	RN/CORF	L051A	0.51	0.85	67%
L052A	Audiologist	BLS 29-1181	0.52	0.92	77%
L053A	RN/Speech Pathologist	L051A, L055A	0.53	0.87	64%
L054A	Vascular Technologist*	BLS 19-1040	0.54	1.07	98%
L055A	Speech Pathologist	BLS 29-1127	0.55	0.90	64%
L056A	RN/OCN*	BLS 29-2033	0.79	0.88	11%
L057A	Genetics Counselor	BLS 29-9092	0.57	0.92	62%
L057B	Behavioral Health Care Manager	BLS 21-1018	0.57	0.57	0%
L063A	Medical Dosimetrist*	BLS 19-1040	0.63	1.07	70%
L107A	Medical Dosimetrist/Medical Physicist	L063A, L152A	1.08	1.45	35%
L152A	Medical Physicist	BLS 19-2012 (75th percentile)	1.52	1.80	18%

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We are proposing to use the 75th percentile of the average wage data for the Medical Physicist (L152A) clinical labor type because we believe this level

would most closely fit with the historic wage data for this clinical labor type. A Medical Physicist is a specific type of physicist, and the available BLS wage data describes the more general category of physicist which is paid at a lower rate. In this specific case, the 75th percentile more accurately describes the clinical labor type in question based on how it has historically been paid. We are also proposing to maintain the current clinical labor pricing for the Behavioral Health Care Manager (L057B) clinical labor type rather than update it. Although the BLS data reflected a decreased clinical labor rate for the Behavioral Health Care Manager labor type, we do not believe that the typical wages have decreased for this clinical labor type given that every other clinical labor type has increased over the past 5 years since the Behavioral Health Care Manager clinical labor type was created. The Behavioral Health Care Manager labor type was initially established in the CY 2017 PFS final rule (81 FR 80350). It seems more likely that we misidentified the proper BLS category for this clinical labor type than that wages have decreased since 2017. We believe that the clinical labor rate for the Behavioral Health Care Manager should be held constant for CY 2022 pending additional public feedback.

We are soliciting comments on the proposed updated clinical labor pricing. We are particularly interested in additional wage data for the clinical labor types for which we lacked direct BLS wage data and made use of proxy labor categories for pricing. We understand that the clinical labor undertaken by, for example, a Histotechnologist (L037B) is not the same as the clinical labor provided by the Health Information Technologist category of BLS wage data that we employed as a proxy for pricing. Although these occupations are not directly analogous to each other in terms of the work they do, we nonetheless believe that the proposed crosswalks are appropriate in terms of the resulting hourly wage data. We appreciate any additional information that commenters can supply both in terms of direct wage data, as well as identifying the most accurate types of BLS categories that could be used as proxies to update pricing for clinical labor types that lack direct BLS wage data. We isolated the anticipated effects of the clinical labor pricing update on specialty payment impacts by comparing the proposed CY 2022 PFS rates with and without the clinical labor pricing updates in place:

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TABLE 6: Anticipated Clinical Labor Pricing Effect on Specialty Impacts

Specialty	Allowed Charges (mil)	New CL Pricing Change
Portable X-Ray Supplier	$95	10%
Family Practice	$6,020	2%
Endocrinology	$508	2%
General Practice	$412	1%
Hand Surgery	$246	1%
Nurse Practitioner	$5,100	1%
Pediatrics	$67	1%
Geriatrics	$192	1%
Orthopedic Surgery	$3,812	1%
Internal Medicine	$10,730	1%
Psychiatry	$1,112	1%
Pulmonary Disease	$1,654	1%
Physician Assistant	$2,901	1%
Neurology	$1,522	1%
Neurosurgery	$811	1%
Plastic Surgery	$382	0%
Optometry	$1,359	0%
Thoracic Surgery	$352	0%
Nurse Anes / Anes Asst	$1,321	0%
Gastroenterology	$1,757	0%
Obstetrics/Gynecology	$636	0%
General Surgery	$2,057	0%
Cardiac Surgery	$266	0%
Physical/Occupational Therapy	$4,973	0%
Ophthalmology	$5,343	0%
Nephrology	$2,225	0%
Clinical Social Worker	$857	0%
Anesthesiology	$2,020	0%
Multispecialty Clinic/Other Phys	$153	0%
Podiatry	$2,133	0%
Clinical Psychologist	$832	0%
Emergency Medicine	$3,077	0%
Total	$97,008	0%
Chiropractor	$765	0%
Physical Medicine	$1,164	0%
Critical Care	$378	0%
Rheumatology	$548	0%
Colon And Rectal Surgery	$168	0%
Cardiology	$6,871	-1%
Infectious Disease	$656	-1%
Other	$48	-1%
Audiologist	$75	-1%
Urology	$1,810	-1%
Nuclear Medicine	$56	-1%
Pathology	$1,265	-1%
Interventional Pain Mgmt	$936	-1%
Radiology	$5,275	-1%
Otolarngology	$1,271	-1%
Dermatology	$3,767	-1%
Hematology/Oncology	$1,707	-2%
Allergy/Immunology	$247	-2%
Independent Laboratory	$645	-3%
Vascular Surgery	$1,293	-4%

Specialty	Allowed Charges (mil)	New CL Pricing Change
Oral/Maxillofacial Surgery	$79	-4%
Radiation Oncology And Radiation Therapy Centers	$1,809	-4%
Interventional Radiology	$499	-5%
Diagnostic Testing Facility	$748	-6%

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The potential effects of the clinical labor pricing update on specialty payment impacts are largely driven by the share that labor costs represent of the direct PE inputs for each specialty. Specialties with a substantially lower or higher than average share of direct costs attributable to labor would experience significant declines or increases, respectively, if this proposal is finalized. For example, the Family Practice specialty has a higher share of direct costs associated with clinical labor, and payments to services comprising the specialty would be expected to increase as a result of this clinical labor pricing update. In contrast, Diagnostic Testing Facilities have a lower share of direct costs that are associated with clinical labor, and payments to services comprising the specialty would be expected to decrease. Other specialty-level payment impacts for the proposed clinical labor pricing changes are driven by changes in wage rates for a clinical labor category that affects a given specialty more than average. One such example would be the proposed increase of 11 percent for Oncology nurses as opposed to the average increase for nurses of 63 percent. We emphasize that these are not the projected impacts by specialty of all the policies we are proposing in this proposed rule for CY 2022, only the anticipated effect of the isolated clinical labor pricing update, should this clinical labor pricing update be finalized as proposed.

When updates to our payment methodology based on new data produce significant shifts in payment, we often consider whether it would be appropriate to implement the updates through a phased transition across several calendar years. For example, we utilized a 4-year transition for the market-based supply and equipment pricing update concluding in CY 2022. We are considering the use of a similar 4-year transition to implement the clinical labor pricing update. A multi-year transition could smooth out the increases and decreases in payment caused by the pricing update for affected stakeholders, promoting payment stability. However, a phased transition would delay the full implementation of updated pricing and continue to rely in part on outdated data for clinical labor pricing. We discuss a potential 4-year transition for the clinical labor pricing update as an alternative considered in the Regulatory Impact Analysis (section VII.I) of this rule.

e. Proposal To Establish Values for Remote Retinal Imaging (CPT Code 92229), Comment Solicitation for Fractional Flow Reserve Derived From Computed Tomography (CPT Code 0503T), and Comment Solicitation for Codes Involving Innovative Technology

Rapid advances in innovative technology are having a profound effect on every facet of the economy, including in the delivery of health care. Emerging and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. While new services have emerged over the last several years, it is possible that the COVID–19 public health emergency (PHE) could be accelerating the supply and demand for these innovations. Emerging and evolving technologies could be useful tools for improving disparities in care that have been exacerbated by the PHE. Some of these new applications have codes for which innovative technology is substituting for and/or augmenting physician work. For example, the CPT Editorial Panel created CPT code 92229 *(Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral)*, a diagnostic test for diabetic retinopathy that uses a software algorithm, and the RUC provided valuation recommendations which included a retinal camera and an analysis fee for remote imaging. In the CY 2021 PFS final rule (85 FR 84629 through 84630), we considered CPT code 92229 to be a diagnostic service under the PFS, contractor-priced it, and stated that we would have ongoing conversations with stakeholders. The following section will discuss proposed policies to establish RVUs for CPT code 92229, solicit feedback to establish RVUs for CPT code 0503T *(Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model)*, and solicit feedback to help us better understand the resource costs for services involving the use of innovative technologies such as software algorithms and artificial intelligence (AI).

In our discussion of CPT code 92229 in the CY 2021 PFS final rule (85 FR 84629 through 84630), we wrote that as the data used in our PE methodology have aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology. As described earlier in this section, PE resources involved in furnishing services are characterized as either direct or indirect costs. Direct costs of the PE resources involved in furnish a service are estimated for each code and include clinical labor, medical supplies, and medical equipment. Indirect costs include administrative labor, office expenses, and all other expenses. Indirect PE is allocated to each service based on physician work, direct costs, and a specialty-specific indirect percentage. The source of the specialty specific indirect percentage was the Physician Practice Information Survey (PPIS), last administered in 2007 and 2008, when emerging technologies that rely primarily on software, licensing, and analysis fees, with minimal costs in equipment and hardware may not have been typical. Thus, these costs are not well accounted for in the PE methodology.

Consistent with our PE methodology and as we have stated in past PFS rulemaking (83 FR 59557), we have considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is considered to be medical equipment. In the case of CPT code 92229, the hardware is a retinal camera used for remote imaging. Given that indirect costs are based on physician work, direct costs, and

specialty-specific indirect percentages that can include high-cost equipment, our concern is that if we were to consider an analysis fee to be a supply cost, as was recommended by the RUC, it is possible that we would inadvertently allocate too many indirect costs for a supply item that may not require additional indirect expenses. Unlike a piece of equipment, such as the retinal camera, an analysis fee for software does not require physical space in an office or administrative staff hours to maintain it.

However, increasingly, stakeholders have routinely expressed concerns with our policy to consider analysis fees as indirect costs, especially for evolving technologies that rely primarily on these fees with minimal costs in equipment or hardware. In comments in the CY 2021 PFS final rule (85 FR 84629 through 84630) responding to our proposal to price the analysis fee for remote imaging as an indirect cost, stakeholders stated that there would be no service if the software was not used. There are two aspects that distinguish CPT code 92229 from other services. First, most of the RUC's recommended resource costs for CPT code 92229 were for the analysis fee, rather than high-cost equipment or other supplies that require commensurate indirect costs to accommodate for space or administrative labor. Second, the innovative technology incorporated into the service is a software algorithm, which interprets data collected during the test, either augmenting the work of the physician or NPP performing the test, or in some cases replacing at least some work that a physician would typically furnish. In general, it is possible that physician work time and intensity of furnishing care to patients could be affected as more services that involve innovative technologies such as software algorithms or AI become available.

We finalized a policy to establish contractor pricing for CPT code 92229 (85 FR 84629 through 84630) because analysis fees for software algorithms and AI applications are not well accounted for our PE methodology, and to recognize that practitioners do incur resource costs for purchase and ongoing use of the software. We stated that we would continue to seek out new data sources and have ongoing conversations with stakeholders while also considering other approaches to reflect overall resource costs for these technologies in our PE methodology.

As we described in the CY 2021 PFS final rule (85 FR 84498 through 84499), the RAND Corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. RAND has found that the PPIS data last collected in 2007–2008 may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries, and consequently may not accurately capture the indirect PE resources required to furnish services to Medicare FFS beneficiaries. Our experience with the challenge of accurately accounting for resource costs for innovative and emerging technologies such as ongoing service-specific software costs that are included in CPT code 92229 is another reason we continue to be interested in potentially refining the PE methodology and updating the data used to establish RVUs and payment rates under the PFS. We commonly employ a crosswalk to recognize resource costs when we lack the inputs that we would need to calculate work, PE, and/or malpractice RVUs for a service otherwise. When we use a crosswalk to value a service, we substitute the established RVUs for other services with similar resource costs in the physician office setting to set RVUs and the national payment rates for that particular service.

For CY 2022, we are proposing to establish values for CPT code 92229 using our crosswalk approach, and thus this service would no longer be contractor-priced. We continue to believe that the software algorithm present in the analysis fee for CPT code 92229 is not well accounted for in our PE methodology; however, we recognize that practitioners are incurring resource costs for purchase of the software and its ongoing use. We are proposing to use a crosswalk that reflects the overall relative resource costs for this service while we continue to consider potentially refining the PE methodology and updating the data we use to establish PE RVUs under the PFS. Specifically, we are proposing a crosswalk to CPT code 92325 (*Modification of contact lens (separate procedure), with medical supervision of adaptation*), a PE-only code used for the eye, as we believe it reflects overall resource costs for CPT code 92229 in the physician office setting. We recognize that the services described by CPT code 92325 are not the same as the services in CPT code 92229; however, we believe that the total resource costs would be similar across these two codes. We believe that crosswalking the RVUs for CPT code 92229 to a code with similar resource costs allows CMS to recognize that practitioners are incurring resource costs for the purchase and ongoing use of the software employed in CPT code 92229, which would not typically be considered direct PE under our current methodology. We are also soliciting comments on our proposal to crosswalk CPT code 92229 to CPT code 92325, and whether other codes would provide a more appropriate crosswalk in terms of resource costs. In addition, as discussed in section II.E of this proposed rule, we are proposing to use our crosswalk approach for CPT code 77X01 *(Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk) and CPT code 77X03 (Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk, technical calculation only).*

We are aware of other services that use similar innovative technologies to those used for the diagnostic test for diabetic retinopathy and trabecular bone score, and that those technologies also are not well-accounted for in our PE methodology. For CY 2018, the AMA CPT Editorial Panel established four new Category III CPT codes for fractional flow reserve derived from computed tomography (FFRCT): CPT code 0501T *(Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report) CPT code 0502T (Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission); CPT code 0503T (Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic*

simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model); and CPT code 0504T (Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report). FFRCT is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through coronary CT scans. It uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing or treatment (typically, a coronary angiogram). We understand that FFRCT can show through non-invasive imaging whether a beneficiary has coronary artery disease thereby potentially avoiding an invasive coronary procedure. Medicare began payment for CPT code 0503T in the hospital outpatient department setting under the Outpatient Prospective Payment System (OPPS) in CY 2018 (82 FR 59284). For the PFS, we typically assign contractor pricing for Category III codes since they are temporary codes assigned to emerging technology and services. We followed this established process for Category III codes by assigning and listing them as contractor pricing in Appendix B in the CY 2018 PFS final rule (available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1676-F). We have since been trying to understand the costs of the PE resource inputs for CPT code 0503T in the physician office setting. In the CY 2021 PFS final rule, we stated that we found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other innovative forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PE methodology; and that our recent reviews for the overall cost of CPT code 0503T have shown the costs in the physician office setting to be similar to costs reflected in payment under the OPPS (85 FR 84630). For the CY 2021 OPPS/ASC final rule, we found that the geometric mean cost reported by hospital outpatient departments for the service was $804.35 (85 FR 85943). We believe the costs reported under the OPPS are instructive as they reflect actual costs that hospitals incurred in furnishing the service described by CPT code 0503T to Medicare beneficiaries, and, as we stated in the CY 2021 PFS final rule, we believe that these costs would be similar in the physician office setting. Using the geometric mean costs under the OPPS as a proxy, we then searched for services paid under the PFS that could potentially serve as a crosswalk. Specifically, we looked for services paid under the PFS that include only a technical component because CPT code 0503T is a technical component-only service, and that have similar total costs to CPT code 0503T. We identified the following potential crosswalks, and seek public comment on which, if any of them, would be appropriate: CPT code 93455 *(Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography) and CPT code 93458 (Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed).* We are also seeking comment on whether other codes would provide a more appropriate crosswalk in terms of resource costs.

We are also more broadly soliciting public comment to help us better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and AI. Specifically, we are requesting commenters consider the following questions:

- To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work? For example, CPT code 92229 is a PE-only code in which the software algorithm may be substituting for some work of an ophthalmologist to diagnose/detect diabetic retinopathy. CPT code 77X01 is a service in which the trabecular bone score software may be supplementing physician work to predict and detect fracture risk. CPT code 0503T may be both substituting for, and supplementing physician work to detect coronary artery disease.
- How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries? For example, if a new software algorithm or AI technology for a diagnostic test results in a reduction in the amount of time that a practitioner spends reviewing and interpreting the results of a diagnostic test that previously did not involve such software algorithm or AI technology, and if the software algorithm or AI could be considered in part a substitute for at least some physician work, it may follow that the intensity of the service decreases. It is also possible that a software algorithm for a diagnostic test that is supplementing other tests to establish a diagnosis or treatment pathway for a particular condition could result in an increase in the amount of time that a practitioner spends explaining the test to a patient and then reviewing the results.
- How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? As discussed previously, the PPIS data that underlie the PE methodology were last collected in 2007 and 2008, which was prior to the widespread adoption of electronic health records and services that involve care management, non-face-to-face and/or asynchronous remote care; the need to use electronic clinical quality measure data to support quality improvement, disparity identification and resolution, and value based payment; and the emergence of software algorithms and/or AI and other technologies that use data to inform, augment, or replace physician work in the delivery of health care. Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?
- How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for

CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI? For example, it is possible that services that involve software algorithms and/or AI may allow a practitioner to more efficiently furnish care to more Medicare beneficiaries, potentially increasing access to care. Additionally, to what extent have services that involve innovative technology such as software algorithms and/or AI affected access to Medicare-covered services in rural and/or underserved areas, or for beneficiaries that may face barriers (homelessness, lack of access to transportation, lower levels of health literacy, lower rates of internet access, mental illness, having a high number of chronic conditions/frailty, etc.) in obtaining health care?

- Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? As we are considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. For example, section 218(b) of the PAMA required that we establish an Appropriate Use Criteria Program to promote appropriate use of advanced diagnostic imaging services provided to Medicare beneficiaries.[1] To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?
- Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? For example, increased access to services to detect diabetic retinopathy such as the service described by CPT code 92229 could eventually lead to fewer beneficiaries losing their vision. Because CPT code 92229 can be furnished in a primary care practice's office and may not require the specialized services of an ophthalmologist, more beneficiaries could have access to a test, including those who live in areas with fewer ophthalmologists. Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?
- Our proposals to use crosswalks to set values for codes describing diabetic retinopathy and trabecular bone score would allow us to account for overall resource costs involved in furnishing the services. The possible crosswalks for FFRCT may also account for overall resource costs involved in furnishing the service. We also believe it is important to accurately account for resource costs for innovative and emerging technologies such as ongoing service-specific software costs and, as explained above, such costs are not well accounted for in the PE methodology. We continue to be interested in potentially refining the PE methodology and updating the underlying data, including the PPIS data that are the data source that underpins the indirect PE allocation. How might CMS consider updating such data to reflect ongoing advances in technology so that we could establish appropriate relative values without resorting to crosswalks? The RAND Corporation laid out a number of issues for CMS to consider in two reports. We refer readers to RAND's first phase of research, available at *https://www.rand.org/pubs/research_reports/RR2166.html*, and RAND's second phase of research, available at *https://www.rand.org/pubs/research_reports/RR3248.html*.

[1] Appropriate Use Criteria Program. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program.*

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.E. of this proposed rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work

required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *MedicarePhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; final rule (76 FR 73052 through 73055) (hereinafter referred to as the ''CY 2012 PFS final rule with comment period''). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the ''CY 2013 PFS final rule with comment period''), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to as

the ''CY 2009 PFS proposed rule''), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2022 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

In this proposed rule, we are soliciting comments regarding the potentially misvalued codes nominated by the public to inform our decision on whether to establish the codes as potentially misvalued in the CY 2022 PFS final rule. We received public nominations for potentially misvalued codes by February 10th. We display these public nominations on our public website, including the submitter's name and their associated organization to provide full transparency. Among the public nominations that we received this year, one was a request for CMS to review a PE-related input for a code. We refer readers to section II.B. of this proposed rule, Determination of PE RVUs, for further discussion on the PE-related submission. The summary of this year's submissions under the potentially misvalued code initiative are discussed below.

A stakeholder nominated CPT code 22551 (*Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex*) ''and common related services'' as potentially misvalued. Citing the CY 2021 PFS final rule (84 FR 84501) where CMS agreed with the public nomination of CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*) as potentially misvalued, and discussed the relationship between CPT code 22867 and CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root*[*s*], [*e.g., spinal or lateral recess* stenosis]), single vertebral segment; lumbar), this stakeholder suggests that there are additional CPT code values related to spine procedures that are in need of contemporaneous review with CPT code 22867. The stakeholder believes that CMS has an interest in reviewing associated anterior cervical discectomy and fusion (ACDF) procedures as well, and suggests that CPT code 22551 ''and common related services'' can result in cumulative RVUs that do not sufficiently reflect physician work, time, or outcomes.

In their submission, the stakeholder expressed concern that there is a discrepancy between the typical total RVUs for codes billed for vertebral fusion procedures performed using three synthetic cage devices with plate and vertebral fusion procedures performed using three allografts with plate. Both methods of vertebral fusion are described by CPT code 22551 (includes a 90-day global period), which has a work RVU of 25.00. Both methods of vertebral fusion involve two units of CPT code 22552 (*Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace* (*List separately in addition to code for primary procedure*) (*ZZZ global period*)) with a total work RVU of 13.00 (6.50×2); and both methods of vertebral fusion involve 1 unit of CPT code 22846 (*Anterior instrumentation; 4 to 7 vertebral segments* (*List separately in addition to code for primary procedure*) (*ZZZ global period*)) with a work RVU of 12.40. The vertebral fusion method employing three synthetic cage devices with a plate would involve CPT code 22853 (*Insertion of interbody biomechanical device*(*s*) (*e.g., synthetic cage, mesh*) *with integral anterior instrumentation for device anchoring* (*e.g., screws, flanges*), *when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace* (*List separately in addition to code for primary procedure*) (*ZZZ global period*)) for the insertion of synthetic cage devices for a total work RVU of 12.75 (4.25×3), and CPT code 20930 (*Allograft, morselized, or*

placement of osteopromotive material, for spine surgery only (*List separately in addition to code for primary procedure*)) with a work RVU of 0.00 (because Medicare considers this code to be bundled into codes for other services). The stakeholder stated that the total work RVUs for the typical vertebral fusion employing three synthetic cage devices with plate would be 63.15 work RVUs.

In contrast, the stakeholder asserted that the vertebral fusion method employing three allografts with plate involves the same set of services and codes (CPT code 22551 (090 global period) and CPT code 22846 (ZZZ global period)), but instead of CPT codes 22853 or 20930, involve CPT code 20931 (*Allograft, structural, for spine surgery only* (*List separately in addition to code for primary procedure*) (*ZZZ global period*) with a work RVU of 1.81. Altogether, the total work RVUs for CPT codes involved in this vertebral fusion method is 52.21. The stakeholder suggested that this difference in total work RVUs, 63.15 versus 52.21, is evidence that these services are misvalued, and that the total work RVUs do not reflect the differences in the amount of work, resources, and intensity between the two vertebral fusion methods.

This stakeholder's description of the potential misvaluation of CPT code 22551 ''and common related services'' differs from the CMS approach to identifying potentially misvalued services by using certain criteria, as described in the beginning of this section. Our determination that one or more codes are potentially misvalued generally revolves around the specific RVUs assigned to an individual code, or several codes within a family of codes. CMS generally does not examine the summed differences in total RVUs based on billing patterns using different codes in different scenarios, representing different physician work, and then comparing the two methods of a procedure, in this case, the use or non-use, of the synthetic cage devices in the vertebral fusion with removal of the disc in the upper spinal column. We do not believe that the stakeholder has provided support for the premise that CPT code 22551 alone is misvalued, or that any of the codes identified as common related services are misvalued. Therefore, we are not inclined to propose this code as potentially misvalued. However, we welcome additional comment, including any analysis or studies demonstrating that one or more of these codes meet the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or are otherwise potentially misvalued.

A stakeholder nominated CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) as potentially misvalued, as it has not been valued for payment in the non-facility/office setting. This stakeholder did not include in their submission detailed recommendations for the items, quantities, and unit costs for the supplies, equipment types, and clinical labor (if any), that might be incurred in the non-facility/office setting, all of which are key factors when determining potential valuation or mis-valuation of a service. Medicare claims data for 2018, 2019, and 2020 show that CPT code 49436 is solely performed in the facility ambulatory surgical center (ASC) setting. We are not inclined to propose this code as potentially misvalued; however, we welcome additional comment, including any analysis or studies demonstrating that this code meets the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or is otherwise potentially misvalued.

A stakeholder nominated CPT code 55880 (*Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound* (*HIFU*), *including ultrasound guidance*) as potentially misvalued, as it has not been valued in the non-facility/office setting. This stakeholder also did not include in their submission detailed recommendations for items, quantities, and unit costs for the supplies, equipment types, and clinical labor (if any), that might be incurred in the non-facility/office setting, all of which are key factors when determining valuation or mis-valuation. This stakeholder stated that the advances in High Intensity Focused Ultrasound (HIFU) technology toward the destruction of cancerous tissues in the prostate gland have matured to the point where this procedure is now equally as effective and as safe as the cryoablation procedure described by CPT code 55873 (*Cryosurgical ablation of the prostate* (*includes ultrasonic guidance and monitoring*)), which is currently valued in the non-facility/office setting (186.69 total RVUs, approximately $6,514) and has been for approximately 10 years. We note that CPT code 55880 was reviewed and valued in the CY 2021 PFS final rule (85 FR 84614 through 84615) in the facility setting only. Accordingly, we do not have enough claims data for this code to make accurate comparisons to similar codes that may be furnished in non-facility settings. There is no case presented here that constitutes a misvaluation of CPT code 55880, and therefore, we are not inclined to put this code forward as potentially misvalued for CY 2022; however, we welcome additional comment, including any analysis or studies demonstrating that this code meets the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or is otherwise potentially misvalued.

A stakeholder nominated CPT code 59200 (*Insertion cervical dilator* (*e.g., laminaria, prostaglandin*) as potentially misvalued because the direct PE inputs do not include the supply item, Dilapan-S. This stakeholder had sought to establish a Level II HCPCS code for Dilapan-S, but CMS did not find sufficient evidence to support that request. The stakeholder now submits Dilapan-S to be considered as PE supply input to a Level I CPT code(s). This stakeholder seeks to add Dilapan-S to the nonfacility/office PE inputs for CPT code 59200. Specifically, the stakeholder recommends adding 4 rods of Dilapan-S at $80.00 per unit, for a total of $320.00, as a replacement for the current PE supply item, laminaria tent (a small rod of dehydrated seaweed that when inserted in the cervix, rehydrates, absorbing the water from the surrounding tissue in the woman's body), which is currently listed at $4.0683 per unit, with a total of 3 units, for a total of $12.20. We welcome additional comment, including any analysis or studies demonstrating that this code meets the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or is otherwise potentially misvalued.

A stakeholder nominated CPT codes 66982 through 66986 as potentially misvalued, as they have not been valued in the non-facility/office setting. This stakeholder did not submit other details or reasoning to support their nomination. We note that some of these cataract-related procedures were initially reviewed and valued in CY 2020 PFS final rule (84 FR 62751), and that presently, additional codes in this family are scheduled to be reviewed and valued in this CY 2022 PFS proposed rule (we refer readers to section II.E. of this proposed rule, Valuation of Specific Codes). The highest utilization of these cataract codes are CPT code 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis*

(*1-stage procedure*), *manual or mechanical technique* (*e.g., irrigation and aspiration or phacoemulsification*), *complex, requiring devices or techniques not generally used in routine cataract surgery* (*e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis*) *or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation*) and CPT code 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis* (*1-stage procedure*), *manual or mechanical technique* (*e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*). In 2018 and 2019, these services were almost all performed in the ASC facility setting, but based on 2020 claims, the most common setting appears to have shifted to the hospital inpatient or hospital outpatient facility setting. There is no case presented here that constitutes a misvaluation of CPT codes 66982 to 66986, and therefore, we are not inclined to put this code family forward as potentially misvalued for CY 2022; however, we welcome additional comment, including any analysis or studies demonstrating that one or more of these codes meet the criteria listed above under ''Identification and Review of Potentially Misvalued Services,'' particularly in regard to any changes in the resources to providing a service, or are otherwise potentially misvalued.

TABLE 7: Stakeholders' Nominations of CPT Codes as Potentially Misvalued for CY 2022

CPT	CPT Descriptor
22551	Neck spine fuse&remov bel c2
49436	Embedded ip cath exit-site
55880	Abltj mal prst8 tiss hifu
59200	Insert cervical dilator (PE supply)
66982 to 66986	Cataract codes

D. Telehealth and Other Services Involving Communications Technology, and Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services—Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and CY 2021 PFS final rule (85 FR 84502) and in 42 CFR 410.78 and 414.65.

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

a. Proposed Changes to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (42 CFR 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare telehealth services list to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare telehealth services list. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits. Some examples of other clinical benefits that we would consider include the following:
  - Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
  - Treatment option for a patient population without access to clinically appropriate in-person treatment options.
  - Reduced rate of complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process treatment.
  - Decreased pain, bleeding, or other quantifiable symptom.
  - Reduced recovery time.
- *Category 3:* In the CY 2021 PFS final rule (85 FR 84507), we created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis following the end of the PHE for the COVID–19 pandemic. This new category describes services that were added to the Medicare telehealth services list during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under the Category 1 or Category 2 criteria. Services added on a temporary, Category 3 basis would ultimately need to meet the criteria under Category 1 or 2 in order to be permanently added to the Medicare telehealth services list. To add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit

when furnished via telehealth. We considered the following factors:

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns for patient safety if the service is furnished as a telehealth service.

++ Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

++ Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

In the CY 2021 PFS final rule (85 FR 84507), we also temporarily added several services to the Medicare telehealth services list using the Category 3 criteria described above. In this proposed rule, we are considering additional requests to add services to the Medicare telehealth services list on a Category 3 basis using the previously described Category 3 criteria.

The Medicare telehealth services list, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

Beginning in CY 2019, we stated that for CY 2019 and onward, we intend to accept requests through February 10, consistent with the deadline for our receipt of code valuation recommendations from the RUC (83 FR 59491). For CY 2022, requests to add services to the Medicare telehealth services list must have been submitted and received by February 10, 2021. Each request to add a service to the Medicare telehealth services list must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare telehealth services list, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare telehealth services list, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2022

Under our current policy, we add services to the Medicare telehealth services list on a Category 1 basis when we determine that they are similar to services on the existing Medicare telehealth services list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the Medicare telehealth services list that resemble those services already on the Medicare telehealth services list.

We received several requests to permanently add various services to the Medicare telehealth services list effective for CY 2022. We found that none of the requests we received by the February 10th submission deadline met our Category 1 or Category 2 criteria for permanent addition to the Medicare telehealth services list. The requested services are listed in Table 8.

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TABLE 8: Requests for Permanent Addition – Services Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Urodynamics	51741	Complex uroflowmetry (e.g., calibrated electronic equipment)
Biofeedback	90901	Biofeedback training by any modality
	90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
	90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
Neurological & Psychological Testing	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
	96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
	96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
	96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
Therapy Procedures	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97150	Therapeutic procedure(s), group (2 or more individuals)
Physical Therapy Evaluations	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable

Service Type	HCPCS	Long Descriptor
		assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
Therapy Procedures	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
Therapy Personal Care	97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
	97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes
	97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes
Therapy Tests and Measurements	97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes
	97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
	97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
Personal Care	98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient
	98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients
	98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients
Evaluative and Therapeutic Services	92607	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour
	92608	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)
	92609	Therapeutic services for the use of speech-generating device, including programming and modification

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We remind stakeholders that the criterion for adding services to the Medicare telehealth list under Category 1 is that the requested services are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list, and that the criterion for adding services under Category 2 is that there is evidence of clinical benefit if provided as telehealth. As explained below, we find that none of the requested services met the Category 1 criterion.

We received a request to permanently add CPT code 51741 (*Complex uroflowmetry (e.g., calibrated electronic equipment)*) to the Medicare telehealth services list. This CPT code describes the acquisition of uroflowmetric information and analysis of that information. The code includes a technical component and a professional component. The technical component describes the acquisition of the uroflowmetric information when billed as a standalone service. The professional component describes the analysis for the uroflowmetric information when it is billed as a standalone service. As we have explained in previous rulemaking (see 83 FR 59483), the remote interpretation of diagnostic tests is not considered to be a telehealth service under section 1834(m) of the Act or our regulation at § 410.78. We do not believe that the technical component, which would include acquisition of the uroflowmetric

information, would meet the criterion to be added on a Category 1 basis because it is not similar to other services on the Medicare telehealth list. Moreover, we do not believe the uroflowmetric information can be accurately and effectively collected using two-way, audio/video communication technology to the degree that would make the results clinically useful. We believe the patient would need to be in the same location as the equipment; thus, making it impracticable to achieve via telehealth. Due to these concerns, we do not believe that the submitted information demonstrates sufficient clinical benefit to support the addition of CPT code 51741 to the Medicare telehealth services list.

We received a request to permanently add several biofeedback, services, CPT codes 90901, 90912, and 90913, to the Medicare telehealth services list. We do not believe these services are similar to Category 1 services on the Medicare telehealth list in that these services describe the application of electrodes directly to the patient's skin and using them to monitor the patient's response. Therefore, we do not believe they meet the criterion for addition to the Medicare telehealth services list on a Category 1 basis. We also believe that proper application of electrodes and monitoring of the patient's response would require the furnishing practitioner to be in the same physical location as the beneficiary. As such, we do not believe these services would meet the criteria for addition to the Medicare telehealth list on a Category 2 basis. When we reviewed these biofeedback services on a Category 2 basis, we found that the information supplied with the requests was not detailed enough to determine if the objective functional outcomes (that is, Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs) of the telehealth patients) were similar to that of patients treated in person. Moreover, we believe that the ADLs/IADLs alone are not sufficient to determine if these services, when performed via telehealth, demonstrate a clinical benefit to a patient. We would request that stakeholders supply a more comprehensive set of objective data in order to fully illustrate any benefits, to better enable us to evaluate all outcomes.

We received requests to permanently add Neuropsychological/Psychological Testing services, CPT codes 96130–96133 and 96136–96139, to the Medicare telehealth services list. We separately reviewed each of the services in these two code families. In prior years' rulemaking, we have declined to add these services on a Category 1 basis because, in contrast to other services on the telehealth list these services require close observation by the furnishing practitioner to monitor how a patient responds and progresses through the testing (see 81 FR 80197). We continue to believe that this is the case. All of these codes describe services that involve a very thorough observation and testing process, and require the tester to observe the following: Speed of responses; the ability to adjust focus; written, sometimes manual tasks; following tasks that display the patients' visuospatial mapping abilities, pattern recognition, abstraction, calculation—all while appreciating that the patient may be distracted or aided by environmental cues. The tester must also maintain some subjective amount of flexibility to allow the patient to be in their environment. Additionally, the tester has to maintain professional scrutiny through dynamic tasks. Given all of the above, remote observation by the furnishing practitioner to accomplish the testing in question seems impractical and potentially creates the risk of inaccuracies in diagnosis and subsequent treatment. We note that the information supplied by stakeholders did not address these concerns, and as such, we have concerns over patient safety and the ability of these services to be accurately and thoroughly performed via telehealth to demonstrate a clinical benefit to Medicare beneficiaries. Therefore, we do not believe these services meet the Category 2 criteria for permanent addition to the Medicare telehealth list of services. Consequently, we are not proposing to add these services to the Medicare telehealth services list. We encourage stakeholders to submit information addressing the concerns we have stated in any future requests to have these services added to the Medicare telehealth list of services.

We received requests to add Therapy Procedures, CPT codes 97110, 97112, 97116, 97150, and 97530; Physical Therapy Evaluations, CPT codes 97161–97164; Therapy Personal Care services, CPT codes 97535, 97537, and 97542; and Therapy Tests and Measurements services, CPT codes 97750, 97755, and 97763, to the Medicare telehealth services list. In the CY 2017 PFS final rule (81 FR 80198), we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists (PTs), occupational therapists (OTs), and speech-language pathologists (SLPs) are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We also stated in the CY 2017 PFS final rule that, because these services are predominantly furnished by PTs, OTs, and SLPs, we did not believe it would be appropriate to add them to the Medicare telehealth services list at that time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services be added to the Medicare telehealth services list so that payment can be made for them when furnished via telehealth by physicians or practitioners who can serve as distant site practitioners. We stated that, since the majority of the codes are furnished over 90 percent of the time by therapy professionals who are not included on the statutory list of eligible distant site practitioners, we believed that adding therapy services to the Medicare telehealth services list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth. We continue to believe this to be true; however, we reviewed each therapy service separately, and have categorized them together here for convenience as the same set of information accompanied the request for each of these services.

We determined that these services did not meet the Category 1 criteria for addition to the Medicare telehealth services because they are therapeutic in nature and in many instances involve direct physical contact between the practitioner and the patient. In assessing the evidence that was supplied by stakeholders in support of adding these services to the Medicare telehealth services list on a Category 2 basis, we concluded that it did not provide sufficient detail to determine whether all of the necessary elements of the service could be furnished remotely, and whether the objective functional outcomes of ADL and IADL for the telehealth patients were similar to those of patients receiving the services in person. As we stated above when discussing the request to add certain biofeedback services to the telehealth list, we do not believe ADLs and IADLS alone are sufficient to demonstrate clinical benefit to a Medicare beneficiary. We have enumerated above some examples of the types of clinical benefits we would consider when evaluating services using the Category 2 criterion.

Therefore, we do not believe the supplied information demonstrates that the services meet either the Category 1 or the Category 2 criteria. We are not

proposing to add these services to the Medicare telehealth services list. We continue to encourage commenters to supply sufficient data for us to be able to see all measurements/parameters performed, so that we may evaluate all outcomes.

We received requests to add the services in Table 9, and we note that these services are generally not separately payable under the Medicare PFS. Given that these services are not separately payable when furnished in-person, they would not be separately payable when furnished as telehealth. Section 1834(m)(2)(A) of the Act provides that payment for a service when furnished as a telehealth services is equal to the payment when the service is furnished in person. CPT code 90849 has a restricted payment status, indicating that claims must be adjudicated on a case-by-case basis when furnished in-person. Accordingly, any separate payment for that service would require special consideration and not be routine. Therefore, we do not believe this service should be added to the Medicare telehealth list. CPT codes 98960–98962 are bundled services, and therefore, payment for these services is always bundled into payment of other services. For that reason, we are not proposing to add them to the Medicare list of telehealth services.

TABLE 9: Requests for Permanent Addition—Services with Non-paid Status Not Proposed for Addition

Service Type	HCPCS	Long Descriptor	Medicare Payment Status Indicator
Psychotherapy	90849	Multiple-family group psychotherapy	R
Education and Training for Patient Self-Management	98960	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient	B
	98961	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients	
	98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	

We received requests to temporarily add Neurostimulators, CPT codes 95970–95972, and Neurostimulators, Analysis-Programming services, CPT codes 95983 and 95984, to the Medicare telehealth services list using the Category 3 criteria (see Table 10). In their submission, the requestor noted they would conduct a future study and would submit the study data to CMS at a later date. These services are on the expanded telehealth services list for the PHE, but were not added by CMS on a category 3 basis in the CY 2021 PFS final rule. We do not yet have sufficient information to adjudicate whether these services are likely to meet the category 1 or category 2 criteria given additional time on the Medicare telehealth services list, without having evaluated the full data, and we encourage commenters to submit all available information, when available, for future consideration. As a result, we are not proposing to add these services to the Medicare telehealth list of services on a Category 3 basis at this time.

TABLE 10: Requests for Temporary Addition – Services Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Neurostimulators	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
	95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
Neurostimulators, Analysis-Programming	95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
	95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)

c. Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

In the CY 2021 PFS final rule (85 FR 84506), in response to the PHE for COVID–19, we created a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. We included in this category the services that were added during the PHE for COVID–19 for which we believed there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. We recognized that the services we added on a temporary basis under Category 3 would ultimately need to meet the criteria under Categories 1 or 2 in order to be permanently added to the Medicare telehealth services list, and that there was a potential for evidence development that could continue through the Category 3 temporary addition period. We also stated that any service added on a temporary basis under Category 3 would remain on the Medicare telehealth services list through the end of the calendar year in which the PHE for COVID–19 ends.

We added 135 services to the Medicare telehealth list in CY 2020 on an interim basis in response to the PHE for COVID–19 through the interim final rule with comment period (IFC) (March 31st COVID–19 IFC (85 FR 19234–19243) and the subregulatory process established in the May 8th COVID–19 IFC (85 FR 27550–27649). Since the publication of the May 8th COVID–19 IFC, we have added several services to the Medicare telehealth list of services using this subregulatory process (please see *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes* for the list of codes available for telehealth under the PFS). As discussed in the CY 2021 PFS final rule (FR 85 84507), at the conclusion of the PHE for COVID–19, associated waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through the regular notice-and-comment rulemaking process, including the previously established Medicare telehealth services list, as modified by subsequent changes in policies and additions to the telehealth services list adopted through rulemaking. Services that were temporarily added on an interim basis during the PHE for COVID–19 would not be continued on the list after the end of the PHE for COVID–19.

Numerous stakeholders have continued to note that there is uncertainty about when the PHE for COVID–19 may end, and express concerns that the services added to the telehealth list on a temporary basis could be removed from the list before practitioners have had time to compile

and submit evidence to support the permanent addition of these services on a Category 1 or Category 2 basis. To respond to these continuing concerns, we are proposing to revise the timeframe for inclusion of the services we added to the Medicare telehealth services list on a temporary, Category 3 basis. Extending the temporary inclusion of these services on the telehealth list will allow additional time for stakeholders to collect, analyze and submit data on those services to support their consideration for permanent addition to the list on a Category 1 or Category 2 basis.

We propose to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023. This will allow us time to collect more information regarding utilization of these services during the pandemic, and provide stakeholders the opportunity to continue to develop support for the permanent addition of appropriate services to the telehealth list through our regular consideration process, which includes notice-and-comment rulemaking. By keeping these services on the Medicare telehealth services list through CY 2023, we will facilitate the submission of requests to add services permanently to the Medicare telehealth services list for consideration in the CY 2023 PFS rulemaking process and for consideration in the CY 2024 PFS rule.

See Table 11 for a list of services that were added to the Medicare telehealth services list on an interim basis to respond to the PHE for COVID–19, but were not extended on a temporary Category 3 basis in the CY 2021 PFS final rule. Under our current policy, these services will be removed from the Medicare telehealth services list as of the date that the PHE for COVID–19 ends. We recognize that, during the time between the publication of the CY 2021 PFS final rule and this proposed rule, practitioners may have used that time to compile new evidence of clinical benefit to support addition to the Medicare telehealth services list on a category 3 basis, including information that suggests that a certain service would likely meet the category 1 or category 2 criteria if provided with more time. We are soliciting comment on whether any of the services that were added to the Medicare telehealth list for the duration of the PHE for COVID–19 should now be added to the Medicare telehealth list on a Category 3 basis to allow for additional data collection for submission for CMS to consider as part of the rulemaking process described in prior paragraphs.

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TABLE 11: Services Added to the Medicare Telehealth Services List for the Duration of the PHE for COVID-19 but Were not Added to the Medicare Telehealth Services List on a Category 3 Basis

Code family	HCPCS	Long Descriptor	Category
Radiation Oncology	77427	Radiation treatment management, 5 treatments	2
Ophthalmological Services	92002	Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient	2
	92004	Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits	2
	92012	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient	2
	92014	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits	2
Speech, Language, and Audiology Services	92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals	2
	92526	Treatment of swallowing dysfunction and/or oral function for feeding	2
	92570	Acoustic immittance testing, includes tympanometry (impedance testing), acoustic reflex threshold testing, and acoustic reflex decay testing	2
	92587	Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3-6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report	2
	92588	Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report	2
	92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming	2
	92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming	2
	92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming	2
	92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming	2
	92550	Tympanometry and reflex threshold measurements	2
	92552	Pure tone audiometry (threshold); air only	2
	92553	Pure tone audiometry (threshold); air and bone	2
	92555	Speech audiometry threshold;	2
	92556	Speech audiometry threshold; with speech recognition	2
	92557	Comprehensive audiometry threshold evaluation and speech recognition (92553 and 92556 combined)	2
	92563	Tone decay test	2
	92565	Stenger test, pure tone	2
	92567	Tympanometry (impedance testing)	2
	92568	Acoustic reflex testing, threshold	2
	92607	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour	2
	92608	Evaluation for prescription for speech-generating augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes (List separately in addition to code for primary procedure)	2
	92609	Therapeutic services for the use of speech-generating device, including programming and modification	2
	92610	Evaluation of oral and pharyngeal swallowing function	2

Code family	HCPCS	Long Descriptor	Category
	92625	Assessment of tinnitus (includes pitch, loudness matching, and masking)	2
	92626	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); first hour	2
	92627	Evaluation of auditory function for surgically implanted device(s) candidacy or postoperative status of a surgically implanted device(s); each additional 15 minutes (List separately in addition to code for primary procedure)	2
	S9152	Speech therapy, re-evaluation	2
Cardiological Services	93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report	2
	93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)	2
	93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)	2
Ventilation Assistance Management	94002	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day	2
	94003	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day	2
	94004	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day	2
	94005	Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (e.g., assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more	2
	94664	Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, metered dose inhaler or IPPB device	2
Neurological Services	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	2
	95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	2
	95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	2

Code family	HCPCS	Long Descriptor	Category
	95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	2
	95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	2
	96105	Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, e.g., by Boston Diagnostic Aphasia Examination) with interpretation and report, per hour	2
Behavioral Health Services	90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); 30 minutes	2
	96110	Developmental screening (e.g., developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument	2
	96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour	2
	96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)	2
	96125	Standardized cognitive performance testing (e.g., Ross Information Processing Assessment) per hour of a qualified health care professional's time, both face-to-face times administering tests to the patient and time interpreting these test results and preparing the report	2
	96127	Brief emotional/behavioral assessment (e.g., depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument	2
	96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	2
	96170	Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes	2
	96171	Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)	2
	97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes	2
	97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)	2

Code family	HCPCS	Long Descriptor	Category
	97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	2
	97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	2
	97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	2
	97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	2
	97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	2
	97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	2
	97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	2
	97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	2
	0373T	Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2
	0362T	Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.	2
	G0410	Group psychotherapy other than of a multiple-family group, in a partial hospitalization setting, approximately 45 to 50 minutes	2
Physical, occupational, and speech therapy	97150	Therapeutic procedure(s), group (2 or more individuals)	2
	97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	2
	97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes	2
Hospital inpatient services	99221	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.	2

Code family	HCPCS	Long Descriptor	Category
	99222	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
	99223	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
Observation care services	99218	Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
	99219	Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
	99220	Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
	99234	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
	99235	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.	2

Code family	HCPCS	Long Descriptor	Category
	99236	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit.	2
Nursing facility services	99304	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.	2
	99305	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.	2
	99306	Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.	2
	99324	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent with the patient and/or family or caregiver.	2
	99325	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient and/or family or caregiver.	2
	99326	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient and/or family or caregiver.	2

Code family	HCPCS	Long Descriptor	Category
	99327	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.	2
	99328	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.	2
	G9685	Physician service or other qualified health care professional for the evaluation and management of a beneficiary's acute change in condition in a nursing facility. this service is for a demonstration project	2
Home Services	99341	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.	2
	99342	Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.	2
	99343	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.	2
	99344	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.	2
	99345	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.	2
Office/Outpatient services *	99441	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service	2

Code family	HCPCS	Long Descriptor	Category
		provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	
	99442	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion	2
	99443	Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion	2
Critical care services	99468	Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger	2
	99471	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age	2
	99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	2
	99475	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age	2
	99477	Initial hospital care, per day, for the evaluation and management of the neonate, 28 days of age or younger, who requires intensive observation, frequent interventions, and other intensive care services	2
Cardiac and Pulmonary Rehabilitation	G0422	Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session	2
	G0423	Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session	2
	G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day	2

*In the CY 2021 PFS final rule, we stated that no payment would be made for these services when furnished using interactive telecommunications system after the end of the COVID-19 PHE.

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d. Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

The Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260, December 27, 2020) included a number of provisions pertaining to Medicare telehealth services. The Medicare telehealth statute at section 1834(m)(4)(C) of the Act generally limits the scope of telehealth services to those furnished in rural areas and in certain enumerated types of ''originating sites'' including physician offices, hospitals, and other medical care settings. Section 1834(m)(7) of the Act, (as added by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018), specifies that the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply, and includes the patient's home as a permissible originating site, for telehealth services furnished to a patient with a diagnosed substance use disorder (SUD) for treatment of that disorder or a co-occurring mental health disorder. Section 123(a) of Division CC of the CAA amended section 1834(m)(7)(A) of the Act to broaden the scope of services for which the geographic restrictions under section 1834(m)(4)(C)(i) of the Act do not apply and for which the patient's home is a permissible originating site to include telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the end of the PHE for COVID–19.[2]

Section 123(a) of the CAA also added subparagraph (B) to section 1834(m)(7) of the Act to prohibit payment for a telehealth service furnished in the patient's home under paragraph (7) unless the physician or practitioner furnishes an item or service in-person, without the use of telehealth, within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at such times as the Secretary determines appropriate. However, section 123(a) of the CAA added a clarification at section 1834(m)(7)(B)(ii) of the Act that the periodic requirement for an in-person item or service does not apply if payment for the telehealth service furnished would have been allowed without the new amendments. As such, the requirement for a periodic in-person item or service applies only for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder other than for treatment of a diagnosed SUD or co-occurring mental health disorder, and only in locations that do not meet the geographic requirements in section 1834(m)(4)(C)(i) of the Act or when the originating site is the home of the patient, regardless of geography. We are seeking comment on whether we

[2] We note that neither the SUPPORT Act nor the CAA amended section 1862 of the Act. Section 1862(a)(4) of the Act and our corresponding regulation at 42 CFR 411.9 prohibit Medicare payment for services that are not furnished within the United States. Both the originating site and the distant site are subject to the statutory payment exclusion.

should adopt a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not (in other words, the services for which payment was newly authorized by the CAA amendments, and those for which payment was authorized before the CAA amendments), and if so, what that mechanism should be. In the event that we need to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not we are also seeking comment on whether a clarification should be added to the regulation at § 410.78 as follows (which would take into account the other amendments we are proposing to § 410.78):

The requirement that the physician or practitioner must furnish an item or service in person, without the use of telehealth, within a specified time frame shall not apply to telehealth services furnished for treatment of a diagnosed substance use disorder or co-occurring mental health disorder, or to services furnished in an originating site described in paragraphs (b)(3)(i) through (viii) or (xiii) that meets the geographic requirements specified in paragraph (b)(4) other than (b)(4)(iv)(D).

As we noted above, section 123(a) of the CAA amends section 1834(m)(7)(B)(i)(I) of the Act to prohibit payment for telehealth services under that paragraph unless the physician or practitioner furnished an item or service to the patient in person, without the use of telehealth, within 6 months before the first telehealth service. Thereafter, section 1834(m)(7)(B)(i)(II) of the Act leaves the Secretary discretion to specify the times or intervals at which an in-person, non-telehealth service is required as a condition of payment for these telehealth services. Therefore, in order to implement the new statutory requirement to specify when an in-person service is required, we propose that, as a condition of payment for a mental health telehealth service described in section 1834(m)(7)(A) of the Act other than services described in section 1834(m)(7)(B)(ii) of the Act (that is, services for which payment was authorized before the CAA amendments), the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service.

We are also seeking comment on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. We note that the language in the CAA states that the physician or practitioner furnishing the in-person, non-telehealth service must be the same person as the practitioner furnishing the telehealth service. There are several circumstances, however, under which we have historically treated the billing practitioner and other practitioners of the same specialty or subspecialty in the same group as if they were the same individual. For instance, for purposes of deciding whether a patient is a new or established patient, or whether to bill for initial or subsequent visit, practitioners of the same specialty/subspecialty in the same group are treated as the same person. For example, when Physician A and Physician B are of the same specialty and subspecialty and in the same group, if Physician A furnishes an initial critical care service to a patient, and Physician B subsequently furnishes additional critical care services to the same beneficiary for the same condition on the same day, Physician B would bill for a subsequent critical care service rather than an initial critical care visit. As we explain in in section II.F.2 of this proposed rule, because practitioners in the same specialty and same group often cover for one another to provide concurrent services, we believe the total time for critical care services furnished to a patient on the same day by the practitioners in the same group with the same specialty should be reflected as if it were a single set of critical care services furnished to the patient. See section II.F.2 of this proposed rule for further discussion of our current and proposed policies for billing critical care services. Similarly, if Physician A furnished a service to a patient, and then Physician B furnished a service to the patient a few months later, that patient would be considered an established patient with respect to both Physician A and Physician B. For example, Physician B could initiate care management services for the patient as an established patient. An example of guidance to this effect can be found in the Medicare Claims Processing Manual (IOM Pub. 100–04, Chapter 12, § 30.6.7), which defines ''new patient'' as a patient who has not received any professional services, that is, E/M service or other face-to-face service (for example, surgical procedure) from the physician or physician group (same physician specialty) within the previous 3 years, for E/M services.

We note that this manual provision is also consistent with CPT guidance on whether a patient is a new or established patient.[3]

We are interested in comments regarding the extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition. This might occur when practitioners in a group cover for each other when a particular practitioner is unavailable or when a practitioner has left the group, but the beneficiary continues to receive services furnished by the group. In addition, fee-for-time compensation arrangements (formerly referred to as locum tenens arrangements), as described in section 1842(b)(6)(D) of the Act, allow for payment to be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if the first physician is unavailable to provide the services, and the services are furnished pursuant to an arrangement that is either informal and reciprocal, or involves per diem or other fee-for-time compensation for such services.

Recognizing the importance of ensuring access to mental health telehealth services to beneficiaries who are unable to see the same practitioner who furnished the prerequisite in-person services due to the practitioner's unavailability, we are seeking comments on an alternative policy to also allow the prerequisite in-person, non-telehealth service for certain mental health telehealth services to be furnished by a practitioner in the same specialty/subspecialty in the same group when the physician or practitioner who furnishes the telehealth service is unavailable or the two professionals are practicing as a team.

As amended by the CAA, section 1834(m)(7)(B)(i)(II) of the Act specifies that for subsequent mental health telehealth service, an in-person, non-telehealth service is required at such times as the Secretary determines appropriate. We are proposing to require that an in-person, non-telehealth service must be furnished by the physician or practitioner at least once within 6 months before each telehealth service furnished for the diagnosis, evaluation, or treatment of mental health disorders by the same practitioner, other than for

[3] American Medical Association. (2020). *CPT 2021 professional edition*. Chicago, Ill.: American Medical Association.

treatment of a diagnosed SUD or co-occurring mental health disorder, and that the distinction between the telehealth and non-telehealth services must be documented in the patient's medical record. We distinguish between mental health services furnished for a diagnosed SUD or co-occurring mental health disorder and those furnished to beneficiaries without a SUD diagnosis on the basis of ICD–10 diagnosis codes included on claims when the services are billed. We chose this interval because we are concerned that an interval less than 6 months may impose potentially burdensome travel requirements on the beneficiary, but that an interval greater than 6 months could result in the beneficiary not receiving clinically necessary in-person care/observation. The proposed 6-month interval also matches the specified statutory interval for the initial telehealth service. We believe that a 6-month interval strikes an appropriate balance between these competing considerations, but are seeking comment on whether a different interval, whether shorter, such as 3–4 months or longer, such as 12 months, may be appropriate to balance program integrity and patient safety concerns with increased access to care. However, we note that regardless of the time interval we establish, the practitioner is not precluded from scheduling in-person visits at a more frequent interval should such visit be determined to be clinically appropriate or preferred by the patient.

As discussed below in this section of this proposed rule, ''e. Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology,'' we are proposing to revise our regulatory definition of ''interactive telecommunications system'' to permit use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home. Therefore, we are also seeking comment on whether it would be appropriate to establish a different interval for these telehealth services, for the diagnosis, evaluation, or treatment of mental health disorders, other than for treatment of diagnosed SUD or co-occurring mental health disorder, when furnished as permitted through audio-only communications technology.

In any event, we propose that there would need to be an in-person visit within 6 months of any telehealth service furnished for the diagnosis, evaluation, or treatment of mental health disorders (other than for treatment of a diagnosed SUD or co-occurring mental health disorder), and the in-person visit would need to be documented in the patient's medical record. Payment would not be made for these telehealth services unless the required in-person service was furnished within 6 months of the telehealth service.

Given the addition of the home of the individual as a permissible originating site for telehealth services for purposes of diagnosis, evaluation, or treatment of a mental health disorder, we are proposing to revise our regulation at § 410.78(b)(3) to add a new paragraph (xiv) to identify the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the first day after the end of the PHE as defined § 400.200 of our regulations; and to provide that payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months of the telehealth service. We are also proposing to revise our regulation at § 410.78(b)(4)(iv)(D) to specify that the geographic restrictions in § 410.78(b)(4) do not apply to telehealth services furnished for the diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the first day after the end of the PHE as defined in our regulation at § 400.200.

In addition, section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Act to add to the list of permissible telehealth originating sites a rural emergency hospital, which is a new Medicare provider type added by section 125 of the CAA effective beginning in CY 2023.

We are also proposing to amend our regulation at § 410.78, Telehealth services, to conform with the statutory change to include rural emergency hospitals as telehealth originating sites beginning in CY 2023. In accordance with section 1834(m)(4)(C)(ii)(XI) of the Act, as added by section 125(c) of the CAA, we propose to revise § 410.78(b)(3) of our regulations to add a rural emergency hospital, as defined in section 1861(kkk)(2) of the Act, as a permissible originating site for telehealth services furnished on or after January 1, 2023.

e. Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

Section 1834(m) of the Act outlines the requirements for Medicare payment for telehealth services that are furnished via a ''telecommunications system,'' and specifies that, only for purposes of Medicare telehealth services through a federal telemedicine demonstration program conducted in Alaska or Hawaii, the term ''telecommunications system'' includes asynchronous, store-and-forward technologies. We further defined the term, ''telecommunications system,'' in the regulation at § 410.78(a)(3) to mean an interactive telecommunications system, which is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

During the PHE for COVID–19, we used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology. Therefore, for certain services furnished during the PHE for COVID–19, we make payment for these telehealth services when they are furnished using audio-only communications technology. Emergency waiver authority is no longer available after the PHE for COVID–19 ends, and telehealth services will again be subject to all statutory and regulatory requirements.

In the CY 2021 PFS final rule (85 FR 84535), we noted that we continued to believe that our longstanding regulatory definition of ''telecommunications system'' reflected the intent of statute and that the term should continue to be defined as including two way, real-time, audio/video communication technology.

Historically, we have not proposed any permanent modifications to the definition of ''interactive telecommunications system'' to allow for use of audio-only communications technology due to our interpretation of the statutory requirements, as well as concerns over program integrity and quality of care. Specifically, we were concerned that the use of audio-only communications technology for Medicare telehealth services could lead to inappropriate overutilization, and believed that video visualization of the patient generally was necessary to fulfill

the full scope of service elements of the codes included on the Medicare telehealth list. We believe it is reasonable to reassess these concerns, given the now widespread utilization during the PHE for COVID–19 of Medicare telehealth services furnished using audio-only communication technology. Based upon an initial review of claims data collected during the PHE for COVID–19, which describe audio-only telephone E/M services, we observed that the audio-only E/M visits have been some of the most commonly performed telehealth services during the PHE, and that most of the beneficiaries receiving these services were receiving them for treatment of a mental health condition. Given the generalized shortage of mental health care professionals (*https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/technical-documentation-health-workforce-simulation-model.pdf*), and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, we believe beneficiaries may have come to rely upon the use of audio-only communication technology in order to receive mental health services, and that a sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to care.

As explained above, section 123 of the CAA removes the geographic restrictions for Medicare telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder, and adds the patient's home as a permissible originating site for these telehealth services. We also believe that mental health services are different from most other services on the Medicare telehealth services list in that many of the services primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to provision of the service. While we continue to believe that two-way, audio/video communications technology is the appropriate, general standard for telehealth services, and that there may be particular instances where visual cues may help a practitioner's ability to assess and treat patients with mental health disorders, especially where opioids or other mental health medications are involved (for example, visual cues as to patient hygiene, or indicators of self-destructive behavior), we note that stakeholders have suggested to us that the availability of telehealth services for mental health care via audio-only communications technology would increase access to care. This is especially true in areas with poor broadband infrastructure and among patient populations that do not wish to use, do not have access to, and/or are unable to utilize devices that permit a two-way, audio/video interaction. Our preliminary analysis of Medicare claims data, as well as information provided to us by stakeholders on the popularity of these services, indicates that use of interactive communication technology for mental health care would likely continue to be high even beyond the circumstances of the COVID–19 pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth during the PHE for COVID–19, utilization of telehealth for many professional services spiked around April 2020 and has diminished over the ensuing months. In contrast, preliminary analysis of Medicare claims data suggest that, for many mental health services that were permanently and temporarily added to the Medicare Telehealth list, there is a steady utilization trend from April 2020 and thereafter. Furthermore, as described above, according to preliminary analysis of claims data which examined utilization by diagnosis, the codes for audio-only E/M services have been highly utilized during the PHE, particularly for beneficiaries with mental health conditions.

Given these considerations, we now believe that it would be appropriate to revisit our regulatory definition of ''interactive telecommunications system'' beyond the circumstances of the PHE to allow for the inclusion of audio-only services under certain circumstances. Therefore, we are proposing to amend our regulation at § 410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. We believe this proposal is consistent with the expansion of at-home access to mental health telehealth services in section 1834(m)(7) of the Act, as amended by section 123 of the CAA, which required that the beneficiary must have received a Medicare-paid (or payable), in-person item or service from the physician or practitioner furnishing the mental health services through telehealth within 6 months of the first mental health telehealth service. We are proposing to adopt a similar ongoing requirement that an in-person item or service must be furnished within 6 months of such a mental health telehealth service. We reiterate that our proposed policy to permit audio-only telehealth services is limited to services where the home is the originating site. This is because the other enumerated telehealth originating sites are medical settings that are far more likely to have access to reliable broadband internet service. When a patient is located at one of these originating sites, access to care is far less likely to be limited by access to broadband that facilitates a video connection. In contrast, access to broadband, devices, and user expertise to enable a video connection is less likely to be available in the patient's home. As described in prior paragraphs, we also believe that mental health services are distinct from other kinds of services on the Medicare telehealth list in that many of the services do not necessarily require visualization of the patient to fulfill the full scope of service elements.

We are also proposing to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/video telehealth services but are providing the mental health services via audio-only communication technology in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. We believe that this requirement will ensure that mental health services furnished via telehealth are only conducted using audio-only communication technology in instances where the use of audio-only technology is facilitating access to care that would be unlikely to occur otherwise, given the patient's technological limitations or preferences. In the interests of monitoring utilization and program integrity concerns for audio-only telehealth services furnished under the terms of this proposed exception, we are proposing to create a service-level modifier that would identify these mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. The use of this modifier would also serve to certify that the audio-only telehealth service meets the requirements for the exception specified in proposed on § 410.78(a)(3), including that the furnishing physician or practitioner has the capacity to furnish the service using interactive two-way, real-time audio/video communication technology, but instead used audio-only

technology under the conditions specified in the regulation.

We are proposing to amend our regulation at § 410.78(a)(3) to specify that an interactive telecommunications system can include interactive, real-time, two-way audio-only technology for telehealth services furnished for the diagnosis, evaluation, or treatment of a mental health disorder as described under paragraph (b)(4)(D), under the following conditions: The patient is located in their home at the time of service as described at § 410.78 (b)(3)(xiv); the distant site physician or practitioner has the technical capability at the time of the service to use an interactive telecommunications system that includes video; and the patient is not capable of, or does not consent to, the use video technology for the service.

We are seeking comment on these proposals, as well as what, if any, additional documentation should be required in the patient's medical record to support the clinical appropriateness of providing audio-only telehealth services for mental health in the event of an audit or claims denial. Additional required documentation could include information about the patient's level of risk and any other guardrails that are appropriate to demonstrate clinical appropriateness, and minimize program integrity and patient safety concerns.

We are also seeking comment on whether, for purposes of the proposed audio-only mental health telehealth services exception, we should exclude certain higher-level services, such as level 4 or 5 E/M visit codes, when furnished alongside add-on codes for psychotherapy, or codes that describe psychotherapy with crisis. We are seeking comment on whether the full scope of service elements for these codes could be performed via audio-only communication technology. However, we also note that maintaining the availability of these services through audio-only communication technology might give patients access to care needed to address their higher level or acute mental health needs in instances where they are unable to access two-way, audio/video communication technology.

2. Other Non-Face-to-Face Services Involving Communications Technology Under the PFS

a. Expiration of PHE Flexibilities for Direct Supervision Requirements

Under section 1861 of the Act and at § 410.32(b)(3) of the regulations, Medicare requires certain types of services to be furnished under specific levels of supervision of a physician or practitioner, including diagnostic tests, services incident to physician services, and other services. For professional services furnished incident to the services of a billing physician or practitioner (see § 410.26) and many diagnostic tests (see § 410.32), direct supervision is required. Additionally, for pulmonary rehabilitation services (see § 410.47) and for cardiac rehabilitation and intensive cardiac rehabilitation services (see § 410.49), requirements for immediate availability and accessibility of a physician are considered to be satisfied if the physician meets the requirements for direct supervision for physician office services at § 410.26 and for hospital outpatient services at § 410.27. Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service, and we have interpreted this ''immediate availability'' requirement to mean in-person, physical, not virtual, availability.

Through the March 31st COVID–19 IFC, we changed the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246) as it pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the CY 2021 PFS final rule (85 FR 84538 through 84540), we finalized continuation of this policy through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. In that rule, we also solicited comment on issues related to the policy allowing virtual provision of direct supervision, specifically whether there should be any additional guardrails or limitations put in place to ensure patient safety/clinical appropriateness, beyond typical clinical standards, and whether we should consider potential restrictions to prevent fraud or inappropriate use. We also stated that we will consider this and other information as we contemplate future policy regarding use of communication technology to satisfy supervision requirements, as well as the best approach for safeguarding patient safety while promoting use of technology to enhance access.

We also note that the temporary exception to allow immediate availability for direct supervision through virtual presence facilitates the provision of telehealth services by clinical staff of physicians and other practitioners incident to their own professional services. This is discussed in the March 31st COVID–19 IFC (85 FR 19246). This is especially relevant for services such as physical therapy, occupational therapy, and speech language pathology services, since those practitioners can only bill Medicare directly for telehealth services under telehealth waivers that are effective only during the PHE for COVID–19. We note that sections 1834(m)(4)(D) and (E) of the Act specifies the types of clinicians who may furnish and bill for Medicare telehealth services, and include only physicians as defined in section 1861(r) of the Act and practitioners described in section 1842(b)(18)(C) of the Act.

We continue to seek information on whether this flexibility should be continued beyond the later of the end of the PHE for COVID–19 or CY 2021. Specifically, we are seeking comment on the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the PHE, and whether physicians and practitioners anticipate relying on this flexibility after the end of the PHE. We are seeking comment on whether this flexibility should potentially be made permanent, meaning that we would revise the definition of ''direct supervision'' at § 410.32(b)(3)(ii) to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation after the PHE for COVID–19, or if we should continue the policy in place for a short additional time to facilitate a gradual sunset of the policy. We are soliciting comment on whether the current timeframe for continuing this flexibility at § 410.32(b)(3)(ii), which is currently the later of the end of the year in which the PHE for COVID–19 ends or December 31, 2021, remains appropriate, or if this timeframe should be extended through some later date to facilitate the gathering of additional information in recognition that, due to the on-going nature of the PHE for COVID–19, practitioners may not yet have had time to assess the implications of a permanent change in this policy. We also seek comment regarding the possibility of permanently allowing immediate availability for direct supervision through virtual presence using real-time audio/video technology for only a subset of services, as we recognize that it may be inappropriate to allow direct

supervision without physical presence for some services, due to potential concerns over patient safety if the practitioner is not immediately available in-person. We are also seeking comment on, were this policy to be made permanent, if a service level modifier should be required to identify when the requirements for direct supervision were met using two-way, audio/video communications technology.

b. Interim Final Provisions in the CY 2021 PFS Final Rule

In the CY 2021 PFS final rule (85 FR 84536), we finalized the establishment of HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*) on an interim basis. We stated that, given the widespread concerns expressed by commenters about the continuing need for audio-only conversations with patients and our determination that we would not continue to pay for audio-only E/M visits after the conclusion of the PHE (see 85 FR 84533 through 84535 for further discussion of that policy), we believed it would be expedient to establish additional coding and payment for an extended virtual check-in, which could be furnished using any form of synchronous communication technology, including audio-only, on an interim basis for CY 2021. We stated that we believed establishing payment for this service on an interim basis will support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. In that rule, we finalized a direct crosswalk to CPT code 99442, the value of which we believe most accurately reflects the resources associated with a longer service delivered via synchronous communication technology, which can include audio-only communication. Commenters supported the creation and interim final adoption of this service. Commenters stated that, as beneficiaries and practitioners may be reluctant to return to primarily in-person services post-PHE, payment for a longer virtual check-in would be necessary to account for circumstances where more time is spent determining whether an in-person visit is needed beyond the 5–10 minutes accounted for by HCPCS code G2012 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*). Commenters also supported valuing HCPCS code G2252 through a direct crosswalk to CPT code 99442. We agree with commenters that additional time may be needed to assess the necessity of an in-person service given concerns over exposure to illnesses beyond the duration of the PHE for COVID–19 and that current coding may not accurately reflect that time. Based on support from commenters, we are proposing to permanently adopt coding and payment for CY 2022, HCPCS code G2252 as described in the CY 2021 PFS final rule.

E. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the

federal government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work

RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. We also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 13 contains a list of codes and descriptors for which we are proposing work RVUs; this includes all codes for which we received RUC recommendations by February 10, 2021. The proposed work RVUs, work time and other payment information for all CY 2022 payable codes are available on the CMS website under downloads for the CY 2022 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*).

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 14 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we addressed certain refinements that would be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We noted that for each refinement, we

indicated the impact on direct costs for that service. We noted that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also noted that many of the refinements listed in Table 14 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also noted that the direct PE inputs for CY 2022 are displayed in the CY 2022 direct PE input files, available on the CMS website under the downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the CY 2022 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2022 we received invoices for several new supply and equipment items. Tables 16 and 17 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 16 and 17 also include the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services; and the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap; are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2022 are available on the CMS website under downloads for the CY 2022 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (DRA) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare OPD fee schedule amount established under the prospective payment system (PPS) for hospital outpatient department services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under paragraph (t)(2)(D) of such section, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor [under the PFS], for the fee schedule amount for such technical component for such year. As required by the section 1848(b)(4)(A) of the statute, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2022, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined above for purposes of this cap. Beginning for CY 2022, we are proposing to include the following services on the list of codes to which the OPPS cap applies: CPT codes 0633T (*Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material*), 0634T (*Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)*), 0635T (*Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)*), 0636T (*Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)*), 0637T (*Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)*), 0638T (*Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)*), 0648T (*Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session*), 0649T (*Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)*), 77X01 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk*), 77X02

(*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk, technical preparation and transmission of data for analysis to be performed elsewhere*), 77X03 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk, technical calculation only*), 77X04 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk interpretation and report on fracture risk only, by other qualified health care professional*), 9111X (*Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), colon, with interpretation and report*), and 933X0 (*3D echocardiographic imaging and postprocessing during transesophageal echocardiography or transthoracic echocardiography for congenital cardiac anomalies for the assessment of cardiac structure(s) (e.g., cardiac chambers and valves, left atrial appendage, intraterial septum, interventricular septum) and function, when performed*). We believe these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

4. Proposed Valuation of Specific Codes for CY 2022

(1) Anesthesia for Cardiac Electrophysiologic Procedures (CPT Code 00537)

In October 2019, the RUC reviewed CPT code 00537 (*Anesthesia for cardiac electrophysiologic procedures including radiofrequency ablation*) and recommended that the code be surveyed for the October 2020 meeting. This service was identified by the RUC via the high volume growth screen for services with total Medicare utilization of 10,000 or more that have increased by at least 100 percent from 2009 through 2014. Additionally, at the October 2019 RUC meeting, the RUC approved an anesthesia reference service list (RSL) and a method to assess the relativity among services on the anesthesia fee schedule that uses a revised building block methodology and a regression line analysis. The RUC has stated that the revised building block methodology generates ''proxy RVUs'' that are then compared against the RSL regression line to assess relativity among anesthesia services. The RUC has indicated that their primary and approved method for anesthesia base unit valuation continues to be the anesthesia survey results, and that the building block and regression line analysis are used as a supplemental validation measure.

The RUC recommended a valuation of 12 base units for CPT code 00537.We disagree with the RUC-recommended valuation of 12 base units for CPT code 00537. After performing a RUC database search of codes with similar total times and post-induction period procedure anesthesia (PIPPA) times, 12 base units appears to be on the very high range. We are proposing a valuation of 10 base units supported by reference codes CPT code 00620 (*anesthesia for procedures on the thoracic spine and cord, not otherwise specified*) and CPT code 00600 (*Anesthesia for procedures on cervical spine and cord; not otherwise specified*), which both have a valuation of 10 base units. CPT code 00620 has a very similar total time of 235 minutes and CPT code 00600 has a higher total time of 257 minutes and the same base unit value of 10, which indicates that this is an appropriate valuation. Additionally, we note that the survey total time for CPT code 00537 increased from 150 to 238 minutes, resulting in a survey result 25th percentile valuation of 10 base units.

We are proposing the RUC-recommended direct PE inputs for CPT code 00537.

(2) Anesthesia Services for Image-Guided Spinal Procedures (CPT Codes 01XX2, 01XX3, 01XX4, 01XX5, 01XX6, and 01XX7)

In 2017, the RUC identified CPT code 01936 (*Anesthesia for percutaneous image guided procedures on the spine and spinal cord; therapeutic*) as possibly needing refinement due to inaccurate reporting via the high volume growth screen. The Relativity Assessment Workgroup reviewed data on what procedures were reported with this anesthesia code. In October 2019, the Workgroup reviewed this service and recommended that it be referred to the CPT Editorial Panel to create more granular codes. In October 2020, the CPT Editorial Panel replaced CPT codes 01935 and 01936 with six new codes to report percutaneous image-guided spine and spinal cord anesthesia procedures. These CPT codes are 01XX2 (*Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic*), 01XX3 (*Anesthesia for percutaneous image guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral*), 01XX4 (*Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic*), 01XX5 (*Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral*), 01XX6 (*Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures (e.g., Kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic*) and 01XX7 (*Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures (e.g., Kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral*).

We are proposing the RUC-recommended valuation of 4 base units for CPT codes 01XX2, 01XX3, 01XX4, and 01XX5.

We disagree with the RUC-recommend valuation of 6 base units for CPT codes 01XX6 and 01XX7. After performing a RUC database search of codes with similar total times and post-induction period procedure anesthesia (PIPPA) times, 6 base units for CPT codes 01XX6 and 01XX7 appears to be a high valuation. We are proposing a valuation of 5 base units for both codes supported by a reference code, CPT code 00813 (*Anesthesia for combined upper and lower gastrointestinal endoscopic procedures, endoscope introduced both proximal to and distal to the duodenum*). CPT code 00813 has a valuation of 5 base units with a higher PIPPA time of 40 minutes as well as a higher total time of 70 minutes. The RUC notes that CPT codes 01XX6 and 01XX7 should have a higher base unit valuation than the other similar codes within this family due to the complex nature of these procedures that have a more intensive anesthesia process. The RUC supports their recommendation with a crosswalk code, CPT code 00732 (*Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum; endoscopic retrograde cholangiopancreatography (ECRP)*). CPT code 00732 has a valuation of 6 base units, a total time of 100 minutes, and a PIPPA time of 65 minutes. CPT codes 01XX6 and 01XX7 have a total time of 58 minutes and a PIPPA time of 20 minutes. We agree that a more complex procedure may require a higher base unit valuation within a code family; however, given the disparity in total and PIPPA time, we disagree with the use of

this crosswalk code to support a valuation of 6 base units and instead propose a valuation of 5 base units supported by reference CPT code 00813, which has higher times and the same base unit valuation.

We are proposing the RUC-recommended direct PE inputs for all six codes in the family.

(3) Closed Treatment of Nasal Bone Fracture (CPT Codes 21315 and 21320)

We agree with the RUC's recommendation to change CPT codes 21315 (*Closed treatment of nasal bone fracture; without stabilization*) and 21320 (*Closed treatment of nasal bone fracture; with stabilization*) to 000-day global period codes from 010-day global period codes to account for the degree of swelling within 10 days post-procedure, and because the patient can remove their own splint at home for CPT code 21320. For CPT codes 21315 and 21320, we disagree with the RUC-recommended work RVUs of 2.00 and 2.33, respectively, as we believe these values do not adequately reflect the surveyed reductions in physician time and the change to a 000-day global period from a 010-day global period for these CPT codes. We are proposing a work RVU of 0.96 for CPT code 21315 and 1.59 for CPT code 21320 based on the reverse building block methodology to remove the RVUs associated with the 010-day global period and the surveyed reductions in physician time. We believe that the proposed work RVU of 0.96 for CPT code 21315 adequately accounts for the 50 percent decrease in intraservice and postservice time, a 31-minute decrease in total time, and a change to a 000-day global period which will allow for separately billable E/M visits as medically necessary. We believe that the proposed work RVU of 1.59 for CPT code 21320 adequately accounts for the 5-minute decrease in intraservice time, 3-minute decrease in total time, and 48 percent decrease in postservice time. Absent an explicitly stated rationale for an intensity increase for CPT codes 21315 and 21320, we are proposing to adjust the work RVU to reflect significant decreases in surveyed physician time.

The global period changes from 010-day to 000-day allow for separately billable E/M visits relating to CPT codes 21315 and 21320, therefore we removed RVUs that we believed were attributable to the currently bundled E/M visits totaling 1.30 RVUs for CPT code 21315 and 0.35 RVUs for CPT code 21320. CPT code 21315 is currently bundled with one post-operative follow up office visit, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter*). CPT code 21320 is currently bundled with half of a post-operative follow up office visit, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*). We do not believe the RUC adequately accounted for the loss of these E/M visits in their recommended work RVUs for CPT codes 21315 and 21320. The RUC's recommendations also seem to dismiss the significant changes in surveyed physician time, without a persuasive explanation of a significant increase in IWPUT that results from the RUC's recommended work RVUs for CPT codes 21315 and 21320. We believe the surveyed decreases in physician time in conjunction with the loss of the post-operative visits for CPT codes 21315 and 21320 merit decreases in the work RVUs from the current work RVUs.

We considered using a modified total time ratio methodology given the age and potentially flawed methodology used to arrive at the current valuation. The modified total time ratio calculation does not include the loss of 8 minutes of post-operative time attributable to the change from a 010-day global period to a 000-day global period for CPT code 21320 and loss of 23 minutes of post-operative time for CPT code 23215. This modified time ratio methodology reflects how the physician time is changing in the pre-, intra-, and postservice periods when a code's global period is changing, given that E/M services can be billed as medically necessary and appropriate for a 000-day global code. The total time ratio between the current and proposed total times for CPT code 21315, excluding the 23 minutes of post-operative time in the current total time, equals 1.64. We arrived at 1.64 by modifying the original total time ratio equation to equal the proposed new total time divided by the current time, less any time attributable to the post-operative global period, then multiplied by the current work RVU. The current total time for CPT code 21315 without the 23 minutes of post-operative time that will be lost by going from a 010-day to a 000-day global period code is 76 minutes, therefore, the modified total time ratio = (68 minutes/(99 minutes − 23 minutes)) * 1.83 = 1.64. When using the original total time ratio methodology for CPT code 21315, it shows a 31 percent decrease in total time [(68 minutes − 99 minutes)/99 minutes = −0.31], whereas the modified methodology shows that there is only an 11 percent decrease in newly proposed pre-, intra-, and postservice time from the current times [(68 minutes − 76 minutes)/76 minutes = −0.11]. The same modified total time ratio methodology could be applicable to CPT code 21320. The current total time for CPT code 21320 without the 8 minutes of post-operative time that will be lost by going from a 010-day to a 000-day global period code is 70 minutes, therefore, the modified total time ratio = (75 minutes/(78 minutes − 8 minutes) * 1.88 = 2.01. The modified methodology shows that the pre-, intra-, and postservice time is increasing by 7 percent for CPT code 21320, whereas the original methodology, which accounts for the loss of the 8 post-operative minutes in the total time ratio, shows a 4 percent decrease in total time that would indicate the need for a work RVU decrease. We recognize that we have not previously used a modified total time approach to consider work RVU values when there is a change in the global period for a service in conjunction with significant surveyed changes to the pre-, intra-, and postservice times; therefore, we are seeking comment on application of the modified total time ratio approach to value services that have a global period change and significant surveyed physician time changes. We believe this methodology may account for the loss of post-operative visits and the surveyed changes in the pre-, intra-, and postservice times in this unique situation, given the potentially flawed methodology used to arrive at the current valuations for CPT codes 21315 and 21320 that are used in the total time ratios.

We are also proposing the RUC-recommended direct PE inputs without refinements and the surveyed physician times for CPT codes 21315 and 21320.

(4) Insertion of Interlaminar/Interspinous Device (CPT Code 22867)

We are proposing the RUC-recommended work RVU of 15.00 for CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*). The RUC is not recommending changes to the current

PE inputs, and CMS is not proposing any changes to the current PE inputs.

(5) Treatment of Foot Infection (CPT Codes 28001, 28002, and 28003)

Through a screen of codes with 010-day global period service with more than one post-operative follow-up office visit, the RUC identified this family of major surgical codes that did not have consistent global periods. The RUC conducted a survey of these codes as 000-day globals for their April 2020 meeting, and the review was postponed until October 2020. CPT code 28001 (*Incision and drainage, bursa, foot*) (work RVU of 2.78 with 31 minutes of intraservice time) currently has a 010-day global period with one post-operative follow-up office visit, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*). Survey results from podiatrists and orthopedic surgeons yielded a median work RVU of 2.00 with 17 minutes of preservice evaluation time, 3 minutes of preservice positioning time, 5 minutes of preservice scrub/dress/wait time, 20 minutes intraservice time, and 15 minutes immediate postservice time for a total of 60 minutes total time. We are proposing the RUC-recommended work RVU of 2.00 and the surveyed physician times for this 000-day global code.

CPT code 28002 (*Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space*) (work RVU of 5.34 with 30 minutes of intraservice time) currently has a 010-day global period with two post-operative follow-up office visits, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*); and a half day hospital discharge CPT code 99238 (*Hospital discharge day management; 30 minutes or less*). For CPT code 28002, the RUC recommended 30 minutes of preservice evaluation time, 5 minutes of preservice positioning time, 15 minutes of preservice scrub/dress/wait time, 30 minutes of intraservice time, and 20 minutes of immediate postservice time, for a total of 100 minutes total time. The RUC recommended a work RVU of 3.50 and the surveyed physician times for this 000-day global code.

We note that the result from the survey's 50th percentile work RVU was 3.73 and that the survey's 25th percentile work RVU was 2.80. As this CPT code is converting from a 010-day global to a 000-day global we find the reference CPT code 43193 (*Esophagoscopy, rigid, transoral; with biopsy, single or multiple*) as a more suitable value of 2.79 work RVUs with a similar 30 minutes of intraservice physician time and 106 minutes of total time. We are proposing a work RVU of 2.79 for CPT code 28002 and we are proposing the RUC surveyed physician times for this 000-day global code.

CPT code 28003 (*Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas*) currently has a 090-day global period with two post-operative follow-up office visits, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*); three post-operative follow-up office visits, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family.*); one post-operative CPT code 99231 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit*); one post-operative CPT code 99232 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit*), and one hospital discharge CPT code 99238 (*Hospital discharge day management; 30 minutes or less*), for a total of eight post op follow-up visits, across five types of E/M and hospital care codes. For CPT code 28003, the RUC recommends 40 minutes of preservice evaluation time, 10 minutes of preservice positioning time, 15 minutes of preservice scrub/dress/wait time, 45 minutes of intraservice time, and 20 minutes of immediate postservice time, for a total time of 130 minutes. We are proposing the RUC-recommended work RVU of 5.28 and surveyed physician times for this 000-day global code.

In order to complete the adjustments for making these Treatment of Foot Infection codes consistent as 000-day global codes, the RUC adjusted the PE inputs for these codes to reflect their proposed global periods from 010 and 090-day globals to 000-day global, and to reflect the use of more typical supplies, equipment, and clinical labor

employed now, than what was necessary a decade ago. Some relatively small valued supply items were removed, while other items were added, and clinical labor times were largely adjusted to remove minutes from the post-operative follow-up office visit times in the 010 and 090-day global codes. We are proposing all of the PE refinements as recommended by the RUC for these codes, which can be found in section II.B. of this proposed rule, under the Determination of Practice Expense RVUs.

(6) Percutaneous Cerebral Embolic Protection (CPT Codes 33XXX)

CPT code 33XXX (*Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous (List separately in addition to code for primary procedure)*) was created in October 2020, by the CPT Editorial Panel as a new add-on code to report transcatheter placement and subsequent removal of cerebral embolic protection device(s). The CPT Editorial Panel also added instructions to report the new code in the Aortic Valve guidelines. The RUC reviewed the survey results for the new add-on code and noted that the survey respondents likely overvalued the physician work involved in performing this service, with a 25th percentile work value of 3.43. The RUC recommends a work RVU of 2.50 for CPT code 33XXX.

We are proposing the RUC-recommended work RVU of 2.50 for CPT code 33XXX. This is a facility-based add-on code with no direct PE inputs.

(7) Exclusion of Left Atrial Appendage (CPT Codes 33XX3, 33XX4, and 33XX5)

In May 2020, the CPT Editorial Panel approved the creation of three new codes to describe open and thoracoscopic left atrial appendage management procedures when performed as stand-alone procedures or in conjunction with other procedures. The codes represent new technology and surgical techniques that may be used to treat atrial fibrillation at the time of another surgical procedure and include CPT code 33XX3 (*Exclusion of left atrial appendage, open, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip*), CPT code 33XX4 (*Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip*) (*List separately in addition to code for primary procedure*)), and CPT code 33XX5 (*Exclusion of left atrial appendage, thoracoscopic, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip*). CPT codes 33XX3 and 33XX5 are 090-day global codes while CPT code 33XX4 is a ZZZ global code.

In October 2020, the RUC reviewed and recommended work and PE values for the three new codes. Recommended work values include 18.50 RVUs for CPT code 33XX3, 2.50 work RVUs for CPT code 33XX4, and 14.31 work RVUs for CPT code 33XX5.

We are proposing the RUC-recommended work RVUs for the three new codes. We are also proposing the RUC-recommended direct PE inputs for CPT codes 33XX3 and 33XX5. We note that CPT code 33XX4 has no direct PE inputs.

(8) Endovascular Repair of Aortic Coarctation (CPT Codes 338X1, 338X2, and 338X0)

In October 2020, the CPT Editorial Panel created CPT codes 338X1 (*Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches*) and 338X2 (*Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches*) to report endovascular stent repair of coarctation of the thoracic or abdominal aorta; and CPT code 338X0 (*Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta*) to report trans-liminal angioplasty for repair of native or recurrent percutaneous coarctation of the aorta. For CY 2022, the RUC recommended a work RVU of 21.70 for CPT code 338X1, a work RVU 17.97 for CPT code 338X2, and a work RVU 14.00 for CPT code 338X0.

We disagree with the RUC-recommended work RVUs for the CPT code family of 338X1, 338X2, and 338X0. We found that the recommended work RVUs for these CPT codes were high when compared to other codes with similar time values. Therefore, we are proposing the RUC survey 25th percentile of 18.27 as the work RVU for 338X1, we are proposing a work RVU of 14.54 for 338X2, and we are proposing a work RVU of 10.81 for 338X0.

When we reviewed CPT code 338X1, we found that the recommended work RVU was high compared to other codes with similar time values. The RUC survey 25th percentile of 18.27 falls within the range of RVUs with similar intra service time. This is supported by the reference CPT codes we compared to CPT code 338X1 with intra service time similar to the 134 minutes of intra service time for CPT code 338X1; reference CPT code 37231 (*Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed*) has a work RVU of 14.75 with 135 minutes of intra service time, and CPT code 93590 (*Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve*) has a work RVU of 21.70 with 135 minutes of intra service time. We note that the RUC-recommended RVU of 21.70 is a crosswalk from CPT code 93590 and is the highest value code within the range of reference codes we reviewed with similar intra service time. Again, we believe the RUC survey 25th percentile of 18.27 is a more appropriate value overall than 21.70 when compared to the range of codes with similar intra service time.

The RUC-recommended RVU of 17.97 for CPT code 338X2 was higher than other codes with the same 120 minutes of intra service time and similar total time. Although we disagree with the RUC-recommended work RVU for 338X2, we concur that the relative difference in work between CPT codes 338X1 and 338X2 is equivalent to the RUC-recommended interval of 3.73 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we are proposing a work RVU of 14.54 for CPT code 338X2, based on the RUC-recommended interval of 3.73 RVUs below our proposed work RVU of 18.27 for CPT code 338X1.

The RUC-recommended work RVU of 14.00 for CPT code 338X0 was higher than other codes with the same 90 minutes of intra service time and similar total time and we believe it would be more accurate to propose a work RVU that maintains the 3.73 incremental difference between the codes in this family. Therefore, for CPT code 338X0, we propose a work RVU of 10.81 which also continues the 3.73 incremental difference used between CPT codes 338X1 and 338X2, instead of the RUC incremental difference of 3.97 between CPT codes 338X2 and 338X0. Although

the work RVU of 10.81 we are proposing for CPT code 338X0 is lower than the RUC recommendation, the 3.73 incremental difference between CPT codes 338X2 and 338X0 we are proposing is more generous than the RUC incremental difference of 3.97 between CPT codes 338X2 and 338X0.

We are proposing no direct PE inputs for the CPT code family of 338X1, 338X2, and 338X0, as recommended by the RUC. These services are provided exclusively in the facility setting.

(9) Harvest of Upper Extremity Artery (CPT Codes 35XX0 and 35600)

In May 2020, the CPT Editorial Panel created CPT code 35XX0 (*Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic*) to describe endoscopic radial artery harvest via an endoscopic approach, and CPT code 35600 (*Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, open*) was modified to only include an open approach for the upper extremity harvesting procedure. The RUC also stated that CPT codes 35XX0 and 35600 are almost always exclusively performed in conjunction with coronary artery bypass grafting (CABG) procedures. For CY 2022, the RUC-recommended a work RVU of 3.75 for CPT code 35XX0 and a work RVU of 4.00 for CPT code 35600.

We disagree with the RUC-recommended RVUs for the CPT code family of 35XX0 and 35600. We found that the recommended work RVUs for these CPT codes were high when compared to other codes with similar time values. Therefore, we are proposing 3.34 as the work RVU for 35XX0 and we are proposing a work RVU of 3.59 for 35600.

We disagree with the RUC-recommended work RVU for CPT code 35XX0 and are proposing an RVU of 3.34 which is a direct work RVU crosswalk from CPT code 35686 (*Creation of distal arteriovenous fistula during lower extremity bypass surgery (non-hemodialysis) (List separately in addition to code for primary procedure)*). The RUC-recommended value of 3.75 is higher than other codes with similar intra service time and total time. This is supported by the reference CPT codes we compared to CPT code 35XX0 with the same 35 minutes of intra service time and 35 minutes of total time as CPT code 35XX0; reference CPT code 74713 (*Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)*) has a work RVU of 1.85, and CPT code 35686 has a work RVU of 3.34.

Although we disagree with the RUC-recommended work RVU for CPT code 35600, we concur that the relative difference in work between CPT codes 35XX0 and 35600 is equivalent to the RUC-recommended interval of 0.25 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we are proposing a work RVU of 3.59 for CPT code 35600, based on the RUC-recommended interval of 0.25 RVUs above our proposed work RVU of 3.34 for CPT code 35XX0.

We are proposing no direct PE inputs for the CPT code family of 35XX0 and 35600 as recommended by the RUC. These services are provided exclusively in the facility setting.

The RUC acknowledged that CPT codes 35XX0 and 35600 are almost always exclusively performed in conjunction with coronary artery bypass grafting (CABG) procedures. Such codes are designated as add-on procedures and are assigned a ZZZ-day global period (that is, code related to another service and is always included in the global period of the other service). The RUC also requested that the global period for both CPT codes 35XX0 and 35600 be an XXX-day global period (that is, global concept does not apply) and not a ZZZ-day global period as is customary for add-on codes. The RUC stated that an XXX-day global period would allow the individual that performs the harvest of upper extremity artery procedure (often separate from the surgeon performing the base CABG procedure) to report it under their own provider number. The RUC noted that it is often a nurse practitioner (NP) or physician's assistant (PA) who performs the harvest procedure. However, the RUC surveyed CPT codes 35XX0 and 35600 using reference codes with the ZZZ-day global period. Therefore, we believe it is appropriate to use that same ZZZ-day global period for CPT codes 35XX0 and 35600, and we are proposing to assign the ZZZ-day global period to CPT codes 35XX0 and 35600 for CY 2022. Through our scrutiny of comparing the code descriptions of codes with matching intra service times, we find much more clinically coherent similarities with codes with a ZZZ-day global period (procedures complementary, and sometimes necessary, to complete a larger procedure) than codes with an XXX-day global period.

However, we are compelled to understand more about the billing circumstances presented by the RUC and stakeholders that have presented this approach for CPT codes 35XX0 and 35600 to CMS for consideration. We are seeking comments and requesting information that may inform why CPT codes 35XX0 and 35600 should have an XXX-day global period instead of the ZZZ-day global period that is customary for add-on codes.

(10) Needle Biopsy of Lymph Nodes (CPT Code 38505)

CPT code 38505 (*Biopsy or excision of lymph node(s); by needle, superficial (e.g., cervical, inguinal, axillary)*) was identified in October 2019 as Harvard Valued with a utilization of over 30,000 claims. In January 2020, the RUC recommended that the code be surveyed for October 2020 RUC meeting. The RUC recommended increasing the work RVU to 1.59 which is the survey 25th percentile, acknowledging a change in the service, which now involves larger tissue samples as well as a change in technology, and a change in the dominant specialty now reporting the service.

We are proposing the RUC-recommended work RVU of 1.59 for CPT code 38505. We are also proposing the RUC-recommended direct PE inputs for this code.

(11) Drug Induced Sleep Endoscopy (CPT Codes 42XXX)

CPT code 42XXX (*Drug induced sleep endoscopy; with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing; flexible, diagnostic*) is a new code created to report drug induced sleep endoscopy (DISE) flexible, diagnostic. The RUC recommended, and we agree, that the survey 25th percentile for the work RVU of 1.90 accurately reflects the typical physician work necessary to perform this service.

Since this is a drug induced sleep endoscopy, we are proposing CPT code 31575 (*Diagnostic laryngoscopy*) as the endoscopic base code for CPT code 42XXX because the description of the proposed CPT code is the same as what is described for CPT code 31575 with the additional component of the patient being sedated. The procedure is performed with a flexible endoscope or laryngoscope. CPT code 42XXX is not an add-on code, it has a 0-day global period. The endoscopic base code that it is using is a specific type of multiple procedure discount that applies to some endoscopy codes.

We are proposing the RUC-recommended work RVU of 1.90 for

CPT code 42XXX. We are also proposing the RUC-recommended direct PE inputs for this code.

(12) Per-Oral Endoscopic Myotomy (POEM) (CPT Codes 434XX)

In May 2020, the CPT Editorial Panel created a new CPT code 434XX (*Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])*) to describe a Per-Oral Endoscopic Myotomy (POEM), which involves the visualization and dissection of the esophageal muscle layers via an endoscope to treat esophageal motility disorders such as achalasia. This procedure accomplishes a comparable myotomy to what traditional open and laparoscopic myotomy (Heller) accomplishes. POEM utilizes an endoscope and specially designed dissecting, cutting, and cauterizing instruments to create a long submucosal tunnel beginning in the mid-esophagus and extending several centimeters into the cardia. For CY 2022, the RUC recommended a work RVU of 15.50 for CPT code 434XX.

We disagree with the RUC-recommended work RVU for CPT code 434XX and are proposing a work RVU of 13.29 based on a direct work RVU crosswalk from CPT code 36819 (*Arteriovenous anastomosis, open; by upper arm basilic vein transposition*). CPT code 36819 has the same 120 minutes of intra service time as CPT code 434XX, and has 283 minutes of total time, which is 2 minutes more than the 281 minutes of total time than for 434XX. The RUC used CPT codes 43279 (*Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed*) and 43180 (*Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (e.g., Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed*) as reference codes for CPT code 434XX. However, the intra service time of 150 minutes and total time of 404 minutes for the RUC reference CPT code 43279, and intra service time of 60 minutes and total time of 201 minutes for the RUC reference CPT code 43180, are not adequate comparisons since they do not have similar time values to those of CPT code 434XX. Therefore, we believe the proposed work RVU of 13.29 for CPT code 434XX based on a direct work RVU crosswalk from CPT code 36819 is a better representation of the work being performed and is more appropriate based on the same intra service time and similar total time.

We are proposing the RUC-recommended direct PE inputs for CPT code 434XX without refinement.

(13) Placement-Removal of Seton (CPT Codes 46020 and 46030)

For CPT codes 46020 (*Placement of seton*) and 46030 (*Removal of anal seton, other marker*), we disagree with the RUC-recommended work RVUs of 3.50 and 2.00, respectively, as we believe these values do not adequately reflect the surveyed reductions in physician time for CPT code 46020 and the change to a 000-day global period from a 010-day global period for these CPT codes. Instead, we are proposing a work RVU of 1.86 for CPT code 46020 and 1.48 for CPT code 46030 based on a reverse building block methodology.

The survey showed that total time and intraservice time are decreasing for CPT code 46020 by 26 minutes and 5 minutes, respectively. We believe the surveyed decreases in physician time in conjunction with the loss of the post-operative visits for CPT code 46020 merit a decrease in work RVU from the current work RVU.

We note that the proposed work RVU of 1.48 for CPT code 46030 falls between CPT code 57410 (*Pelvic examination under anesthesia (other than local)*), which has a work RVU of 1.75, and CPT code 64487 (*Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed)*), which has a work RVU of 1.48. Both of these bracketing reference codes have identical intraservice times and similar total time values. While we understand that total time is going up for CPT code 46030, this increase is a result of significant increases to evaluation, positioning, and scrub, dress, wait preservice times, which is mostly low-intensity physician work.

We agree with the RUC's recommendation to change CPT codes 46020 and 46030 to 000-day global period codes from 010-day global period codes to account for the highly variable follow-up care for these services, but we note that the differences in RUC-recommended work RVUs and our proposed work RVUs largely reflect the change in global period and loss of physician time to provide the E/M services. The global period changes from 010-day to 000-day allow for separately billable E/M visits relating to CPT codes 46020 and 46030, therefore we removed RVUs that we believed were attributable to the currently bundled E/M visits totaling 2.04 RVUs for CPT code 46020 and 0.35 RVUs for CPT code 46030. CPT code 46020 is currently bundled with two post-operative follow up office visits, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*), and a half hospital discharge CPT code 99238 (*Hospital discharge day management; 30 minutes or less*). CPT code 46030 is currently bundled with half of a post-operative follow up office visit, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10–19 minutes of total time is spent on the date of the encounter*). We do not believe the RUC adequately accounted for the loss of these E/M visits in their recommended work RVUs for CPT codes 46020 and 46030.

The RUC proposed the standard 090-day preservice times for the clinical labor activities CA001, CA002, CA003, CA004, and CA005 for CPT code 46020 in the facility. We note that the RUC recommended 090-day preservice clinical labor times despite surveying the service as a 000-day service. We disagree with the RUC-recommended 090-day preservice clinical labor times as we believe 000-day services should have times consistent with 000-day services, not 090-day services. However, we recognize there is time needed to coordinate this service. Therefore, we are proposing the following standard clinical labor times for extensive use of clinical staff for a 000-day global code:

- Complete preservice diagnostic and referral forms (CA001) 5 minutes.
- Coordinate pre-surgery services (including test results) (CA002) 10 minutes.
- Schedule space and equipment in facility (CA003) 5 minutes.
- Provide preservice education/obtain consent (CA004) 7 minutes.
- Complete pre-procedure phone calls and prescription (CA005) 3 minutes.

We are also proposing to refine the direct PE input for Coordinate post-procedure services (CA038) to 0 minutes from the RUC-recommended 3 minutes to align with 000-day standards instead of 090-day standards for CPT code 46020.

For CPT code 46030, the RUC recommended the standard 000-day

extensive use of clinical staff preservice times for clinical activities CA001, CA002, CA003, CA004, and CA005 in the facility and non-facility settings. Preservice times for 000-day codes are presumed to be zero unless there is sufficient justification that preservice time is warranted. We do not agree that sufficient justification was presented to warrant preservice time in the non-facility setting, therefore, we are proposing the following standard clinical labor times for use of clinical staff in the non-facility setting. We are also proposing the standards for minimal use of clinical staff in the facility setting, as we recognize there is time needed to coordinate this service for CPT code 46030:

- Complete preservice diagnostic and referral forms (CA001) 0 minutes for non-facility and 3 minutes for facility.
- Coordinate pre-surgery services (including test results) (CA002) 0 minutes for non-facility and 3 minutes for facility.
- Schedule space and equipment in facility (CA003) 0 minutes for non-facility and 3 minutes for facility.
- Provide preservice education/obtain consent (CA004) 0 minutes for non-facility and 3 minutes for facility.
- Complete pre-procedure phone calls and prescription (CA005) 0 minutes for non-facility and 3 minutes for facility.

We are also proposing to refine the direct PE input for Coordinate post-procedure services (CA038) to 0 minutes from the RUC-recommended 3 minutes to align with 000-day standards instead of 090-day standards for CPT code 46030.

(14) Periurethral Balloon Continence Device Procedures (CPT Codes 53XX1, 53XX2, 53XX3, and 53XX4)

In October 2020, the CPT Editorial Panel replaced four CPT Category III codes with four new CPT Category I codes to report periurethral adjustable balloon continence devices. Given the low utilization and the low survey response rate for the four new codes, the RUC recommended that CMS assign contractor pricing to these procedures. We agree with the RUC and we are proposing contractor pricing for all four codes in the family, CPT codes 53XX1 (*Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance*), 53XX2 (*Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance*), 53XX3 (*Periurethral transperineal adjustable balloon continence device; removal, each balloon*) and 53XX4 (*Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume*).

(15) Intracranial Laser Interstitial Thermal Therapy (LITT) (CPT Codes 617X1 and 617X2)

In October 2020, the CPT Editorial Panel approved the addition of two codes to report laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance (MR) imaging guidance for a single trajectory for 1 simple lesion and multiple trajectories for multiple or complex lesion(s). LITT is a novel procedure that involves multiple steps and movements of the patient through the hospital for different stages of the procedure. The typical facility does not have an interoperative MRI suite (a small minority of academic medical centers may), so patient transport is necessary.

The RUC recommended a work RVU of 20.00 for CPT code 617X1 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*) based on the survey median response. CPT code 617X1 was surveyed with having one subsequent hospital visit, CPT code 99232 (*sbsq hospital care/day 25 minutes*) and 40 minutes of immediate postservice time. The RUC noted that although the survey median immediate postservice time was 40 minutes, for 617X1, the CMS 23-Hour Stay Outpatient Surgical Services with Subsequent Hospital Visits Policy was applied which resulted in the 99232 visit being removed and its 20 minutes of intraservice time being applied to the 40 minutes of immediate postservice time resulting in 60 minutes of immediate postservice time. See the 2011 PFS final rule (75 FR 73226) for an in-depth explanation of the 23-hour policy. We believe the RUC partially applied the 23-hr policy when it applied the policy to the immediate post service time but not to the work RVU. We believe the 23-hour policy in its entirety should be applied to 671X1, which includes the work RVUs along with the immediate postservice time.

Following the valuation methodology we established for 23-hour stay services in the CY 2011 PFS final rule, 617X1 would have a work RVU of 19.06.

The steps are as follows:

- *Step (1):* CPT code 617X1 does not have a hospital discharge day management service; therefore, we would skip this step.
- *Step (2):* 20 − 1.39** = 18.61.
- *Step (3):* 18.61 + (20 minutes × 0.0224)*** = 19.06 RVUs.

* Value associated with 1/2 hospital discharge day management service.

** Value associated with an inpatient hospital visit, CPT code 99232.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

Therefore, for CY 2022 we are proposing a work RVU of 19.06 for CPT code 671X1.

In reviewing the RUC-recommended direct PE inputs for 671X1 we noticed the RUC proposed the standard 090-day preservice times for the following clinical labor activities:

- Complete preservice diagnostic and referral forms (CA001) 5 minutes.
- Coordinate pre-surgery services (including test results) (CA002) 20 minutes.
- Schedule space and equipment in facility (CA003) 8 minutes.
- Provide preservice education/obtain consent (CA004) 20 minutes.

Complete pre-procedure phone calls and prescription (CA005) 7 minutes.

We note that the RUC recommended 090-day preservice times despite surveying the service as a 000-day service. We disagree with the RUC-recommended 090-day times as we believe this is a 000-day service and should have times consistent with 000-day services. However, we recognize there is time needed to coordinate this service. Therefore, for CY 2022 we are proposing the following standard clinical labor times for a 000-day extensive:

- Complete preservice diagnostic and referral forms (CA001) 5 minutes.
- Coordinate pre-surgery services (including test results) (CA002) 10 minutes.
- Schedule space and equipment in facility (CA003) 5 minutes.
- Provide preservice education/obtain consent (CA004) 7 minutes.
- Complete pre-procedure phone calls and prescription (CA005) 3 minutes.

For CPT code 617X2 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)*), the RUC recommended a work RVU of 24.00 which is the survey median. The RUC's recommendation also included 40 minutes of immediate postservice time and one hospital visit, CPT code 99233 (*sbsq hospital care/day visit 35 minutes*). We believe it would be appropriate to apply the 23-hr policy to CPT code 617X2 as well.

The steps are as follows:

- *Step (1):* CPT code 617X2 does not have a hospital discharge day management service. Therefore, we would skip this step.
- *Step (2):* 24 − 2** = 22
- *Step (3):* 22 + (30 minutes × 0.0224)*** = 22.67 RVUs

* Value associated with 1/2 hospital discharge day management service.

** Value associated with an inpatient hospital visit, CPT code 99233.

*** Value associated with the reallocated intraservice time multiplied by the postservice intensity of the 23-hour stay code.

This results in a work RVU of 22.67, and an immediate post service time of 70 minutes. Therefore, for CY 2022 we a proposing a work RVU of 22.67 and 70 minutes of immediate postservice time for CPT code 617X2.

For the direct PE, the RUC proposed identical preservice times for CPT codes 617X1 and 617X2. For the reasons stated above concerning the direct PE inputs for CPT code 671X1, we are proposing the standard clinical labor times associated with a 000-day extensive for CPT code 617X2 for CY 2022.

(16) Arthrodesis Decompression (CPT Codes 630XX and 630X1)

For CPT codes 630XX (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess* stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)) and 630X1 (*Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)*), we disagree with the RUC-recommended work RVUs of 5.55 and 4.44, respectively, because these values are anomalously high in comparison to other similar add-on codes that have longer intraservice times, and we are proposing a work RVU of 3.08 for CPT code 630XX and a work RVU of 2.31 for CPT code 630X1.

CPT codes 630XX and 630X1 are new add-on codes to report decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace. The proposed work RVU for CPT code 630XX is based on an intraservice time ratio between the proposed 40 minutes of intraservice time for CPT code 630XX and the 45 minutes of intraservice time for CPT code 63048 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*). We believe that CPT code 63048 is a stronger reference code for CPT code 630XX than the RUC-recommended reference CPT codes 33924 (*Ligation and takedown of a systemic-to-pulmonary artery shunt, performed in conjunction with a congenital heart procedure (List separately in addition to code for primary procedure)*) and 22614 (*Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)*) because of the similarities in the long descriptors, physician time, and intensity of intraservice work for CPT codes 630XX and 63048. The intraservice time ratio between CPT codes 63048 and 630XX equals a work RVU of 3.08 for CPT code 630XX ((40 minutes/45 minutes) * 3.47 = 3.08). Therefore, we are proposing a work RVU of 3.08 for CPT code 630XX. The intraservice time ratio between CPT codes 63048 and 630XX was selected to value CPT code 630XX because of the similarities in the descriptions of intraservice work provided in the RUC's summary of recommendations for CPT code 630XX and the RUC Database for CPT code 63048. We are proposing a work RVU of 2.31 for CPT code 630X1 based on an intraservice time ratio between the proposed 30 minutes of intraservice time for CPT code 630X1 and the proposed 40 minutes of intraservice time for CPT code 630XX ((30 minutes/40 minutes) * 3.08 = 2.31), given that the RUC contends that there are some efficiencies in providing an additional level of decompression, evidenced by the 10 minutes less of intraservice time for CPT code 630X1 compared to CPT code 630XX. These work RVU proposals are further supported by brackets of other 30 and 40 minute ZZZ codes.

We note that the proposed work RVU for CPT code 630XX falls between CPT code 19294 (*Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (List separately in addition to code for primary procedure)*), which has a work RVU of 3.00, and CPT code 37185 (*Primary percutaneous transluminal mechanical thrombectomy, noncoronary, non-intracranial, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)*), which has a work RVU of 3.28. Both of these bracketing reference codes have identical intraservice times as CPT code 630XX. The proposed work RVU for CPT code 630X1 falls between CPT code 43273 (*Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s) (List separately in addition to code(s) for primary procedure)*), which has a work RVU of 2.24, and CPT code 22870 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)*), which has a work RVU of 2.34. Both of these bracketing reference codes have identical intraservice times as CPT code 630X1. When we compared the RUC-recommended work RVU of 5.55 for CPT code 630XX and 4.44 for CPT code 630X1 to other spinal add-on codes in the 63000 CPT code series in the RUC database, we found that CPT code 630XX would have the highest work RVU and the second shortest intraservice time (with CPT code 630X1 having the shortest intraservice time), and CPT code 630X1 would have the third highest work RVU and shortest intraservice time compared to the 10 other nationally-priced spinal add-on codes in the 63000 CPT code series. We do not agree that decompression when performed in conjunction with posterior interbody arthrodesis at the same interspace should have an anomalously high work value in comparison to other similar add-on codes that have longer intraservice times. We believe that our proposed work RVUs of 3.08 for CPT code 630XX and 2.31 for CPT code 630X1 better serve the interests of relativity. We note that the specialty societies did not survey the two new add-on codes with the base codes, which is a standard to provide assurance that the respondents followed instruction to only consider the work of the add-on codes. CPT codes 630XX and 630X1 were reviewed again with their base codes at the April 2021 RUC meeting. There were also revisions to the base codes' definitions, guidelines, and parenthetical instructions, which

were approved by the CPT Editorial Panel for CY 2022.

The RUC did not recommend any direct PE inputs for these codes and we are not proposing any direct PE inputs.

(17) Hypoglossal Nerve Stimulator Services (CPT Codes 645X1, 645X2, and 645X3)

In October 2020, the CPT Editorial Panel added three new CPT Category I codes to report open implantation, revision or replacement, and removal of hypoglossal nerve stimulator array. These new CPT codes replaced three CPT Category III codes which were reported with CPT codes 64568 *(Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator*), 64569 *(Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator)* and 64570 *(Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator).*

CPT code 645X1 (*Open implantation of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array*) was previously reported using the now deleted Category III CPT code 0466T *(Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure))* along with CPT code 64568. We are not proposing the RUC-recommendation to use the survey median work RVU of 16.00 for CPT code 645X1. We are proposing a work RVU of 14.00 based on the intraservice time ratio of CPT code 64568 compared to the RUC-recommended intraservice time for CPT code 645X1. CPT code 64568 has a work RVU of 9.00, intraservice time of 90 minutes and total time of 275 minutes. CPT code 645X1 has a RUC-recommended work RVU of 16.00, intraservice time of 140 minutes and total time of 294 minutes. Additionally, when we reviewed CPT code 645X1, we found that the RUC-recommended work RVU was higher than other global 90-day codes with similar time values. We do not agree that it would be typical to value this code so much higher than services with similar work time values. Additionally, we note that the proposed work RVU of 14.00 is also the survey 25th percentile. Therefore, as previously stated, we believe 14.00 is a more appropriate value overall than 16.00 when compared to the range of codes with similar work times.

We are not proposing the RUC-recommended work value of 16.50 for CPT code 645X2 *(Revision or replacement of hypoglossal nerve neruostimulator array and distal respiratory sensor electrode or electrode array, including connection to an existing pulse generator)*, rather we are proposing a work RVU of 14.50. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 645X1 and 645X2 is equivalent to the recommended increment of 0.50 RVUs. Therefore, we are proposing a work RVU of 14.50 for CPT code 645X2 based on the recommended increment of 0.50 additional RVUs above our proposed work RVU of 14.00 for CPT code 645X1. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Additionally, we note that the proposed work RVU of 14.50 is also nearly identical to the 25th percentile survey value for CPT code 645X2 of 14.63. Therefore, as previously stated, we believe 14.50 is a more appropriate value than 16.50 to maintain an appropriate intra-family relativity.

We are not proposing the RUC-recommended work value of 14.00 for CPT code 645X3 *(Removal of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array)*, rather we are proposing a work RVU of 12.00. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 645X1 and 645X3 is equivalent to the recommended increment of −2.0 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we are proposing a work RVU of 12.00 for CPT code 645X3 based on the recommended increment of 2.0 RVUs below our proposed work RVU of 14.00 for CPT code 645X1. Additionally, we note that the proposed work RVU of 12.00 is also the RUC 25th percentile survey value for CPT code 645X3.

We are proposing the RUC-recommended direct PE inputs without refinements for CPT codes 645X1, 645X2 and 645X3.

(18) Destruction by Neurolytic Agent (CPT Codes 64633, 64634, 64635, and 64636)

In September 2014, the Relativity Assessment Workgroup identified a work neutrality issue for CPT codes 64633 (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic*, single facet joint), 64634 (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint (List separately in addition to code for primary procedure))*, 64635 (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint),* and 64636 *(Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint (List separately in addition to code for primary procedure))* related to incorrect coding relative to how the services were originally valued. In May 2015, the CPT Editorial Panel revised the parenthetical instructions for the five codes describing paravertebral facet joint nerve destruction to clarify that these codes are reported per joint, not nerve. Due to the extensive growth and original incorrect assumptions about distribution of reporting, the RUC recommended that CPT codes 64633–64636 be surveyed. We are proposing the RUC-recommended work RVU of 1.32 for CPT code 64634 and the RUC-recommended work RVU of 1.16 for CPT code 64636.

For CPT codes 64633 and 64635, we are not proposing the RUC-recommended work RVU of 3.42 for both codes, as we believe this value understates the decrease in physician work time for these codes. An analysis of all 010-day global period codes indicates that these proposed values would place these codes among the highest valued for codes with similar time values. We are instead using a total-time ratio methodology to propose work RVUs of 3.31 for CPT code 64633 and 3.32 for CPT code 64635. We support these values by noting that they fall between CPT codes 54164 (*Frenulotomy of penis*), with a work RVU of 2.82, and CPT code 68371 (*Harvesting conjunctival allograft, living donor*), with a work RVU of 5.09; these reference codes have total time values that are similar to, and intraservice time values that are identical to those recommended for CPT codes 64633 and 64635.

We are proposing the RUC-recommended direct PE inputs without refinement.

(19) Destruction of Intraosseous Basivertebral Nerve (CPT Codes 646X0 and 646X1)

In October 2020, the CPT Editorial Panel added two Category I codes to report thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance for the first two vertebral bodies (lumbar or sacral) and for each additional vertebral body (lumbar or sacral).

We are not proposing the RUC-recommended work value of 8.25 for CPT code 646X0 (*Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; first two vertebral bodies, lumbar or sacral*). When we reviewed CPT code 646X0, we found that the RUC-recommended work RVU was higher than codes with the same 10-day global period, same intraservice time and similar total times. The RUC-recommended work RVU of 8.25 would value CPT code 646X0 at the 90th percentile of comparable 10-day globals and we do not agree that it would be typical to value this code so much higher than services with similar work time values. We believe it would be more accurate to propose a work RVU of 7.15 based on a crosswalk to CPT code 63650 (*Percutaneous implantation of neurostimulator electrode array, epidural*) with a work RVU of 7.15, identical intraservice time of 60, and similar total time of 170. We believe the crosswalk to CPT code 63650 serves as a more accurate valuation for CPT code 646X0.

We also are not proposing the RUC-recommended work value of 4.87 for CPT code 646X1 (*Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 646X0 and 646X1 is equivalent to the recommended increment of −3.38 RVUs. However, since the recommended work RVU of code 646X0 was higher than other codes with the same 10-day global period, same intraservice time, and similar total times, we refined the work RVU for code 646X1 to preserve the incremental difference between the two codes. We believe that these refinements maintain the relationship between the two codes in the family while better preserving relativity with other similar 10-day global codes on the wider PFS. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of codes where it is important to maintain an appropriate intra-family relativity. Therefore, we are proposing a work RVU of 3.77 for CPT code 646X1 based on the recommended increment of 3.38 RVUs below our proposed work RVU of 7.15 for CPT code 646X0.

We are proposing the RUC-recommended direct PE inputs without refinements for CPT code 646X0. CPT code 646X1 is an add-on code and does not have any direct PE inputs.

(20) Dilation of Aqueous Outflow Canal (CPT Codes 66174 and 66175)

These services were identified through the New Technology/New Services List. In January 2020, the specialty societies submitted an action plan and the RUC recommended referral to the CPT Editorial Panel in 2020 to possibly revise the descriptor and add exclusionary parentheticals for CPT code 66174 (*Transluminal dilation of aqueous outflow canal; without retention of device or stent*). In October 2020, the CPT Editorial Panel revised this code to add a parenthetical to restrict reporting this code in conjunction with CPT code 65820 (*Goniotomy*).

We are not proposing the RUC-recommended work RVUs of 8.53 for CPT code 66174 and 10.25 for CPT code 66175 (*Transluminal dilation of aqueous outflow canal; with retention of device or stent*), as we believe these values do not adequately reflect the surveyed reductions in physician time. These RVUs would rank these codes among the highest valued 090-day global period codes of similar time values. We are proposing a work RVU of 9.34 for CPT code 66175 using a reverse building block methodology. We then subtract the incremental difference between the two RUC-recommended work RVUs, an increment of 1.72, from our proposed work RVU of 9.34 for CPT code 66175 to propose a work RVU of 7.62 for CPT code 66174. We believe this approach is consistent with the RUC's assumption that the intensity and complexity of CPT code 66174 is the same as that of CPT code 66175, the only difference between the two procedures being the additional intraservice time associated with placement of the stent. As further support for these values, we note that they fall between CPT code 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*), with 7.35 work RVUs, and CPT code 15150 (*Tissue cultured skin autograft, trunk, arms, legs; first 25 sq cm or less*), with 9.39 work RVUs.

We are proposing the RUC-recommended PE inputs without refinement.

(21) Cataract Removal With Drainage Device Insertion (CPT Codes 669X1, 669X2, 66982, 66984, 66987, 66988, and 0X12T)

The RUC identified CPT code 0191T (*Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion*) via the Category III codes with High Utilization screen (2018 estimated Medicare utilization over 1,000). In January 2020, the RUC recommended that the specialty societies develop a coding application for Category I status for CPT code 0191T and CPT code 0376T (*each additional device insertion (List separately in addition to code for primary procedure)*. In October 2020, the CPT Editorial Panel replaced two Category III codes (CPT codes 0191T and 0376T) with two new codes, CPT codes 669X1 and 669X2, to report extracapsular cataract removal with insertion of intraocular lens prosthesis and one Category III code to report insertion of anterior segment aqueous drainage device without concomitant cataract removal.

The RUC recommended a work RVU of 12.13 for CPT code 669X1 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more*) based on the survey 25th percentile.

In its recommendation, the RUC noted that the recommended intraservice time of 28 minutes for CPT code 669X1 is 2 minutes less than the intraservice time of 30 minutes associated with CPT code 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual*

or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation). The RUC further noted this should not be the case, as the insertion of the intraocular lens prosthesis should take the same amount of time and be represented by the same relative work for both procedures and that it is counterintuitive that the intraservice time for CPT code 669X1 would be lower than the intraservice time for CPT code 66982, as CPT code 669X1 includes both complex cataract surgery and the insertion of the intraocular anterior segment aqueous drainage device. The specialty society that surveyed the codes explained that this is likely because the early adopters of this new technology service are highly skilled surgeons who would likely perform these procedures quickly. They stated that as this procedure diffuses into the wider population of ophthalmologic surgeons over the next few years, the intraservice time will likely rise above the intraservice time associated with CPT codes 66982 and 66984 and will come in line for both CPT codes 669X1 and 669X2.

CPT code 69982 has a work RVU of 10.25, 125 minutes of total time and 30 minutes of intraservice time. CPT code 669X1 has a RUC-recommended work RVU of 12.13, 176 minutes of total time and 28 minutes of intraservice time. We agree with the RUC assessment that both procedures, CPT code 66982 and CPT code 669X1, are almost identical in time and intensity. However, we disagree with the RUC-recommended work RVU of 12.13 for CPT code 669X1 noting that CPT code 66982 has a work RUV of 10.25. We are proposing a work RVU of 10.31 based on the current total time ratio of CPT code 66982 compared to the RUC-recommended total time for CPT code 669X1.

For CPT code 669X2, the RUC recommended a work RVU of 9.23. The RUC determined that it would be appropriate to use the increment between the 25th percentile work RVU value for CPT code 669X1 and the current RUC-reviewed work RVU value for CPT code 66982 to build a work RVU recommendation for CPT code 669X2. The RUC determined that the increment between the 25th percentile work RVU value for CPT code 669X1 (work RVU = 12.13) and the current RUC-reviewed work RVU value for CPT code 66982 (work RVU = 10.25) would yield an increment between those two codes of 1.88. The RUC added the 1.88 increment to 7.35, the current work RVU for 66984, which yields a RUC-recommended work RVU value of 9.23. This comparison results in a work RVU recommendation of 9.23 for CPT code 669X2. We are proposing a work RVU of 7.41, which is the increment between the current RUC-reviewed work RVU value for CPT code 66982 and CPT code 66984. The increment between CPT code 66982 (work RVU = 10.25) and CPT code 66984 (work RVU = 7.35) yields a work RUV of 2.90. We subtracted this 2.90 increment from 10.31, to determine our proposed work RVU of 7.41 for CPT code 669X1.

We are proposing the RUC-recommended indirect PE values for CPT codes 669X1 and 669X2.

We are not proposing any new valuations but reaffirming the work RVUs and direct PE inputs that we previously finalized for CPT codes 66982 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation*) and 66984 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation*). For CPT codes 66987 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation*) and 66988 (*Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation*) we continue to believe these services should be contractor priced.

(22) Retinal Detachment Prophylaxis (CPT Codes 67141 and 67145)

CPT code 67145 (*Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage, 1 or more sessions; photocoagulation (laser or xenon arc)*) was identified in October 2019 as a Harvard Valued service with utilization over 30,000. In January 2020, the RUC agreed with the specialty societies that surveyed the service and recommended that CPT code 67145, as well as its parent CPT code 67141 (*Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage, 1 or more sessions; cryotherapy, diathermy*), be referred to the CPT Editorial Panel for a descriptor and global period change. The codes were edited to remove the reference to ''1 or more sessions'' so that the services may be valued as a 010-day procedure versus the current 090-day global. At the May 2020 CPT Editorial Panel meeting, the Panel approved revision of the two codes to remove ''1 or more sessions'' from the descriptors and deletion of the Eye and Ocular Adnexa Prophylaxis guidelines.

For CY 2022, we are proposing the RUC-recommended work RVU of 2.53 for CPT codes 67141 and 67145. We are also proposing the RUC-recommended direct PE inputs without refinements.

(23) Strabismus Surgery (CPT Codes 67311, 67312, 67314, 67316, 67318, 67320, 67331, 67332, 67334, 67335, and 67340)

In April 2020, The RUC recommend that add-on CPT codes 67320, 67331, 67332, 67334, 67335, and 67340 be surveyed along with the base codes in which these services are typically reported (CPT codes 67311, 67312, 67314, 67316 and 67318). When AMA staff compiled a list of 010-day and 090-day services for increases in physician work and time during the surgical global period, they noticed that several low volume codes that were converted to ZZZ global periods in 1999 still included office visits (specifically CPT codes 67320, 67331, 67332, 67334, 67340). It appeared that these office visits may not be appropriate for these services. This issue was deferred until October 2020.

We are proposing the RUC-recommended work RVUs for all base codes within this family. This includes a work RVU of 5.93 for CPT code 67311 (*Strabismus surgery, recession or resection procedure; 1 horizontal muscle*), 9.50 for CPT code 67312

(*Strabismus surgery, recession or resection procedure; 2 horizontal muscles*), 5.93 for CPT code 67314 (*Strabismus surgery, recession or resection procedure; 1 vertical muscle (excluding superior oblique),* 10.31 for CPT code 67316 (*Strabismus surgery, recession or resection procedure; 2 or more vertical muscles (excluding superior oblique)*), and 9.80 for CPT code 67318 (*Strabismus surgery, any procedure, superior oblique muscle*).

We are also proposing the RUC-recommend work RVUs for all of the add-on codes within this family. This includes a work RVU of 3.00 for CPT code 67320 (*Transposition procedure (eg, for paretic extraocular muscle), any extraocular muscle (specify) (List separately in addition to code)*), 2.00 for CPT code 67331 (*Strabismus surgery on patient with previous eye surgery or injury that did not involve the extraocular muscles (List separately in addition to code for primary procedure)*), 3.50 for CPT code 67332 (*Strabismus surgery on patient with scarring of extraocular muscles (eg, prior ocular injury, strabismus or retinal detachment surgery) or restrictive myopathy (eg, dysthyroid opthalmopathy) (List separately in addition to code for primary procedure)*), 2.06 for CPT code 67334 (*Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)*), 3.23 for CPT code 67335 (*Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)*), and 5.00 for CPT code 67340 (*Strabismus surgery by posterior fixation suture technique, with or without muscle recession (List separately in addition to code for primary procedure)*).

We are proposing the RUC-recommended direct PE inputs for this code family without refinements.

(24) Lacrimal Canaliculus Drug Eluding Implant Insertion (CPT Codes 68XXX)

CPT code 68XXX (*Insertion of drug-eluting implant, including punctal dilation, when performed, into lacrimal canaliculus, each*) was recommended for RUC review in October 2020 since the CPT Editorial Panel replaced CPT Category III (temporary) code 0356T with a new CPT Category I code to report the insertion of a drug eluting implant into the lacrimal canaliculus. We are proposing the RUC-recommended work RVU of 0.49 for CPT code 68XXX.

For the direct PE inputs, we are proposing to refine the equipment time for the ''lane, screening (oph)'' (EL006) from the RUC-recommended 9 minutes of equipment time to the 5 minute equipment standard for CPT code 68XXX. Five minutes is the standard equipment time associated with EL006 for this procedure. The recommended materials for this code family from the RUC state that the screening lane is used for the duration of setup, procedure, cleaning, and counselling post procedure and that the standard formulas are applied. We believe that the RUC inadvertently failed to update the equipment time associated with this procedure when CPT code 68XXX was reviewed. The recommended materials for CPT code 68XXX state the standard equipment time formula would be typical for this service, which would be 5 minutes in this case (the CA013 and CA024 equipment times are included but not the CA035 equipment time). We are proposing to refine the equipment time for the equipment item lane, screening (oph) (EL006) from 9 minutes to 5 minutes to match this change in equipment time and are seeking additional comment from stakeholders regarding the RUC-recommended non-standard equipment time of 9 minutes. We do not agree that it would be typical for CPT code 68XXX to require an additional 4 minutes of equipment time totaling 9 minutes.

(25) Transcutaneous Passive Implant-Temporal Bone (CPT Codes 69714, 69717, 69X50, 69X51, 69X52, and 69X53)

In October 2020, the CPT Editorial Panel deleted two codes used for mastoidectomy and replaced them with four new codes for magnetic transcutaneous attachment to external speech processor. The CPT Editorial Panel made additional revisions to differentiate implantation, removal, and replacement of the implants.

We are proposing the RUC-recommended work RVU for all six of the codes in this family. We are proposing a work RVU of 8.69 for CPT code 69714 (*Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor*), a work RVU of 9.77 for CPT code 69X50 (*Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor*), a work RVU of 8.80 for CPT code 69717 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor*), a work RVU of 9.77 for CPT code 69X51 (*Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor*), a work RVU of 5.93 for CPT code 69X52 (*Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor*), and a work RVU of 7.13 for CPT code 69X53 (*Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor*).

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Post-operative visits (total time)'' (CA039) activity from the RUC-recommended 108 minutes to 99 minutes for CPT codes 69714 and 69717. 99 minutes is the clinical labor time associated with one Level 2 postoperative office visit and two Level 3 postoperative office visits; we believe that the RUC inadvertently failed to update the clinical labor time associated with these postoperative office visits when CPT codes 69714 and 69717 were reviewed. We are also proposing to refine the equipment time for all equipment items other than the basic instrument pack (EQ137) from 108 minutes to 99 minutes to match this change in clinical labor time.

(26) X-Rays at Surgery Add-On (CPT Code 74301)

The RUC recommended that CPT code 74301 (*Cholangiography and/or pancreatography; additional set intraoperative, radiological supervision and interpretation (List separately in addition to code for primary procedure)*) be deleted for October 2020. The specialty societies that typically bill for this service submitted a code change application to delete CPT code 74301 at the February 2020 CPT meeting. However, the specialty societies withdrew the deletion request after receiving feedback from the dominant provider of CPT code 74301 (general surgery), indicating the code is still necessary and should not be deleted. The RUC recommended to maintain the work RVU of 0.21 for CPT code 74301. The specialty societies did not resurvey CPT code 74301 due to its low utilization (2019 Medicare utilization = 63) and the difficulty of obtaining 30 survey responses from providers with experience in the past 12 months. Since there was no survey done, there is no new information and the RUC recommended to maintain the current value. The work RVU suggested by the RUC is a reaffirmation of the current value.

We are proposing the RUC-recommended work RVU of 0.21 for

CPT code 74301. This is an add-on code with no direct PE inputs.

(27) Trabecular Bone Score (TBS) (CPT Codes 77X01, 77X02, 77X03, and 77X04)

We are proposing the RUC-recommended work RVUs of 0.20 for CPT codes 77X01 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk*) and 77X04 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk interpretation and report on fracture risk only, by other qualified health care professional*). CPT codes 77X02 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere*) and 77X03 (*Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only*) are PE only codes; the RUC did not recommend and we are not proposing a work RVU for these codes.

The RUC PE recommendations for CPT codes 77X01 and 77X03 include a new ''TBS iNsight Software'' supply input. The submitted invoice for this supply indicates that it is a licensing fee associated with the use of the software, which is not typically considered to be a form of direct PE under our methodology. Historically, we have considered most computer software and associated licensing fees to be indirect costs tied to associated costs for hardware considered to be medical equipment. However, as we noted in section II.B. of this proposed rule (the PE section), stakeholders have routinely expressed concerns with this policy, especially for evolving technologies that rely primarily on software and licensing fees with minimal costs in equipment or hardware. Most of the recommended resource costs for CPT codes 77X01 and 77X03 are for this analysis fee and these costs are not well accommodated by the PE methodology since these sorts of technological applications did not exist when the data that underlie the PE allocation was last collected in 2007 through 2008.

We are therefore proposing to value the PE for CPT codes 77X01 and 77X03 through the use of a crosswalk to a comparable service, CPT code 71101 (*Radiologic examination, ribs, unilateral; including posteroanterior chest, minimum of 3 views*), which, for CY 2021, had a PE RVU of 0.94. We are proposing that the PE RVU for CPT code 77X03 equals the PE RVU from code 77X01 minus the PE RVU from codes 77X02 and 77X04 so that the three codes sum to the valuation of code 77X01. (CPT code 77X01 is the global code in this family and CPT codes 77X02, 77X03, and 77X04 must sum together to equal the value of 77X01.) CPT code 71101 is another type of bone imaging procedure that we believe reflects codes 77X01 and 77X03 similar direct PE resource costs as CPT codes 77X01 and 77X03. We recognize that the services being performed in this crosswalk code are not the same as the services in CPT codes 77X01 and 77X03, however we believe that the direct resource costs would typically be analogous across these codes. We believe that this is the most accurate way to incorporate the costs of the software employed in CPT codes 77X01 and 77X03 which would not typically be considered direct PE under our current methodology. We are soliciting comments, both on the specific proposal for the Trabecular Bone Score codes as well as our broader discussion of this topic in section II.B. of this proposed rule.

(28) Pathology Clinical Consult (CPT Codes 80XX0, 80XX1, 80XX2, and 80XX3)

The Relativity Assessment Workgroup identified CPT code 80500 (*Clinical pathology consultation; limited, without review of patient's history and medical records*) via the CMS/Other source codes with the Medicare utilization over 20,000 screen. In October 2019, the RUC referred this issue to the CPT Editorial Panel to define this service more specifically as the current descriptor is vague. In October 2020, the CPT Editorial Panel replaced CPT codes 80500 and 80502 (*Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records*) with four new codes, CPT codes 80XX0 (*Pathology clinical consultation; for a clinical problem with limited review of patient's history and medical records and straightforward medical decision making. When using time for code selection, 5–20 minutes of total time is spent on the date of the consultation. (For consultations involving the examination and evaluation of the patient, see 99241, 99242, 99243, 99244, 99245, 99251, 99252, 99253, 99254, 99255)*), 80XX1 (*for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making. When using time for code selection, 21–40 minutes of total time is spent on the date of the consultation*), 80XX2 (*for a highly complex clinical problem, with comprehensive review of patient's history and medical records and high level of medical decision making. When using time for code selection, 41–60 minutes of total time is spent on the date of the consultation*), and 80XX3 (*prolonged service, each additional 30 minutes (List separately in addition to code for primary procedure) (Use 80XX3 in conjunction with 80XX2) (Do not report 80XX0, 80XX1, 80XX2, 80XX3 in conjunction with 88321, 88323, 88325) (Prolonged pathology clinical consultation service of less than 15 additional minutes is not reported separately) (For consultations involving the examination and evaluation of the patient, see 99241–99255)*) to report pathology clinical consultation and creation of guidelines to select and document the appropriate level of service.

The RUC recommended a work RVU of 0.50 for CPT code 80XX0 based on the 25th percentile of the survey. The RUC-recommended 15 minutes of intraservice and total times for CPT code 80XX0 are 2 minutes above the current instraservice and total times for CPT code 80500. This represents a 15 percent increase in the respective times. However, the RUC-recommended work RVU of 0.50 is 35 percent higher than the current work RVU of 0.37 for CPT code 80500. We believe that the increase or decrease in times should be commensurate with the increase or decrease in the work RVU. Therefore, we are proposing a work RVU of 0.43. This represents the ratio of total time between the current total time of CPT code 80500 and the proposed total time of CPT code 80XX0 (0.15) applied to the current value of CPT code 80500 (0.37 $\times$ 0.15 = 0.43).

We are proposing the RUC-recommended work RVU of 0.91 without refinements for CPT code 80XX1.

The RUC recommended a work RVU of 1.80 for CPT code 80XX2 based on the 25th percentile of the survey. The current intraservice and total times for CPT code 80502 are 42 minutes. The RUC-recommended times for CPT code 80XX2 are 54 minutes. Similar to the scenario described above for CPT code 80XX0, the intraservice and total times for CPT code 80XX2 increased 28.6 percent while the work RVU increased 35 percent. As stated above, we believe the increase or decrease in time should be commensurate with the increase or

decrease in the work RVU. Therefore, for CPT code 80XX2 we are proposing a work RVU of 1.71, which is the current total time ratio of CPT code 80502 compared to the RUC-recommended total time for CPT code 80XX2.

We are proposing the RUC-recommended work RVU of 0.80 for CPT code 80XX3 without refinement.

For the direct PE inputs of CPT codes 80XX0, 80XX1, and 80XX2, we are proposing to refine the time associated with the clinical labor activity PA001 (Accession and enter information) from the RUC-recommended time of 4 minutes to 0 minutes as we believe the time is duplicative with clinical labor activity PA008 (File specimen, supplies, and other materials).

The RUC recommended 15, 30, 54, and 30 minutes of equipment time for EP024 (microscope, compound) for CPT codes 80XX0, 80XX1, 80XX2, and 80XX3, respectively. We note that there is no indication from the code descriptors that the pathologist is reviewing physical slides. The code descriptor and description of work indicate that the pathologist is reviewing paper records and/or EHR and therefore we are proposing to remove the equipment time associated with EP024 (microscope, compound) from CPT codes 80XX0, 80XX1, 80XX2, and 80XX3.

Additionally, the proposed Levels of Decision Making for Table for Pathology Clinical Consult codes includes ''Assessment requiring an independent historian(s)'' as an element of ''Amount and/or Complexity of Data to be Reviewed and Analyzed *—Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1 below.'' Neither the code descriptors nor the descriptions of work indicate that this type of assessment is typical in a pathology clinical consult as was discussed for the office visit Levels of Decision Making table. For these reasons, CMS proposes that this element not be included as an element that CMS would recognize as an element of medical decision making. We note that CMS will monitor the use of these replacement codes per our usual practice to ensure appropriate billing and inform future rulemaking as needed. We are also seeking comment on how these replacement codes would most typically be billed relative to use of existing pathology coding. Such information would also inform future rulemaking as needed.

(29) Revaluing End Stage Renal Disease (ESRD) Monthly Capitation Payment Services (MCP) (CPT Code 90954)

In the CY 2021 PFS final rule (85 FR 84551 through 84554), we revalued most, but not all, of the ESRD MCP services. We finalized an increase in valuations for those ESRD MCP codes with values tied to the values of Outpatient/Office Evaluation and Management (O/O E/M) codes. We did not revalue CPT code 90954 (*End-stage renal disease (ESRD) related services monthly, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*) because it was originally valued by a crosswalk.

Stakeholders stated that CPT code 90954 was different from the other ESRD MCP codes. Rather than using an O/O E/M code building block methodology as had been used originally to value the other ESRD MCP codes, CPT code 90954 was valued based upon a crosswalk to CPT code 99293 (*Inpatient pediatric critical care provided for children age 29 days through 24 months old, per day*). When CPT code 99293 was deleted, the value of CPT code 90954 was crosswalked to a replacement code, CPT code 99471 (*Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age*). By crosswalking CPT code 90954 to CPT code 99471, the rank order across the ESRD MCP code family at that time was preserved.

Since we finalized the revalued ESRD MCP values for CY 2021, stakeholders have requested that we revalue CPT code 90954 because by not updating it, we created a rank order anomaly for work RVUs and time within the ESRD MCP code family. A stakeholder suggested that we address the rank order anomaly by revaluing CPT code 90954 based upon a new crosswalk to CPT code 33977 (*Removal of a ventricular assist device; extracorporeal, single ventricle*). The stakeholder stated that CPT code 33977 more appropriately represented the time and effort of the service provided over one month than the existing crosswalk to CPT code 99471 relative to the revalued services within the MCP code family.

In response to stakeholder requests to update the value of CPT code 90954, we are proposing to increase the value of CPT code 90954, a global code with a current work RVU of 15.98, by crosswalking it to CPT code 33977, a 090-day procedural code with a work RVU of 20.86 to preserve relativity within the ESRD MCP family. We are also seeking comment on our proposal to increase the value of CPT code 90954.

(30) Colon Capsule Endoscopy (CPT Codes 91110, 91111, and 9111X)

In October 2020, the CPT Editorial Panel replaced Category III code 0355T (*Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report*) with a new Category I code 9111X (*Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report*) to report gastrointestinal tract imaging. CPT codes 91110 (*Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report*) and 91111 (*Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report*) were added as part of the family and surveyed for the January 2021 RUC meeting.

We are proposing the RUC-recommended work RVU for two of the codes in this family. We are proposing a work RVU of 2.24 for CPT code 91110 and a work RVU of 2.41 for CPT code 9111X as recommended by the RUC in both cases. For CPT code 91111, we disagree with the RUC-recommended work RVU of 1.00 and we are proposing a work RVU of 0.90 based on a crosswalk to CPT code 95923 (*Testing of autonomic nervous system function; sudomotor, including 1 or more of the following: Quantitative sudomotor axon reflex test (QSART), silastic sweat imprint, thermoregulatory sweat test, and changes in sympathetic skin potential*). CPT code 95923 is an autonomic nervous system testing procedure that shares the identical intraservice work time of 15 minutes with CPT code 91111 and has 5 additional minutes of immediate postservice work time. When we reviewed CPT code 91111, we noted that the surveyed intraservice work time had decreased by 3 minutes, from 18 minutes to 15 minutes, while the RUC recommended maintaining the current work RVU of 1.00. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, decreases in time should typically be reflected in decreases to work RVUs. In the case of CPT code 91111, we believe that it would be more accurate to propose a work RVU of 0.90 based on a crosswalk

to CPT code 95923 to account for these decreases in the surveyed work time.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Prepare, set-up and start IV, initial positioning and monitoring of patient'' (CA016) activity from the RUC-recommended 9 minutes to 6 minutes for CPT code 91111. The recommended materials for this code family state that the 6 minutes for the CA016 activity are used to connect the equipment, fit belt to patient, put data recorder on patient, and sync capsule to each sensor on belt. This description of this clinical labor activity is identical for CPT codes 91110 and 9111X and each code has the same recommended time of 6 minutes. However, the recommended materials for CPT code 91111 state that 6 minutes are used to connect the equipment, fit belt, put data recorder on patient, sync capsule to each sensor and then an additional 3 minutes are used to position the patient (assist patient onto table lying down on right side and then into a sitting position after the capsule is swallowed). We do not agree that it would be typical for CPT code 91111 to require an additional 3 minutes for positioning as compared with the other codes in the family, particularly in light of the clinical similarities between these services. We are refining the clinical labor time to 6 minutes for CPT code 91111 to maintain relativity within the family.

We are also proposing to refine the equipment time for the capsule endoscopy recorder kit (EQ146) from 64 minutes to 61 minutes and the exam table (EF023) from 44 minutes to 41 minutes to match this change in clinical labor time for CPT code 91111.

(31) External Cardiovascular Device Monitoring (CPT Codes 93228 and 93229)

For CPT code 93228 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*), we disagree with the RUC-recommended work RVU of 0.52, and we are proposing a work RVU of 0.43. The proposed work RVU is based on an intraservice time ratio between the current and RUC-recommended intraservice times for CPT code 93228 ((10 minutes/12 minutes)*0.52), yielding a work RVU of 0.43. This proposed work RVU reflects the decrease in total time and is a direct work RVU crosswalk to CPT code 93290 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors*). CPT code 93290 has the same pre-, intra-, and postservice times as the survey times for CPT code 93228 and was reviewed in October 2016. While we recognize that the number of ECG tracings and daily reports have increased because of the increase in average wear time from 14 days to 20 days, the specialty societies and the RUC contend that this is offset by technology advancements, integrations with EHRs, and online portals that make it easier to manage and review the data in a chronological and efficient manner. Therefore, we are recommending a work RVU that accounts for decrease in total time to provide this service, given that the increased tracings and daily reports are offset by the efficiencies gained by technological advancements.

The RUC recommended 10 minutes for ''Provide education/obtain consent'' (CA011) for CPT code 93228, based on a direct crosswalk and duplication of CPT code 93229 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*). We disagree with the RUC-recommended duplication of clinical labor to provide education that the patient will hear for a second time from the IDTF technician. While we understand that the duplication is by design, we do not agree with a direct crosswalk from CPT code 93229, because the provider of CPT code 93229 will likely have more in-depth education, specific to the patient, including materials and instructions for the patient to review. Therefore, we are proposing the standard 2 minutes for CA011 in the non-facility for CPT code 93228.

The RUC recommended the addition of 24 minutes for quality assurance ''overread'' done by a second, senior technician, Clinical Activity Code CA021, Line 67 on the RUC-recommended PE Spreadsheet, for CPT code 93229. This is a new clinical activity for CPT code 93228, and we are seeking public comment about the typicality of a second senior technician. We are requesting additional information about the IDTF's current quality assurance measures and parameters within the ECG recording program that should act as some degree of quality assurance. We are also seeking additional information from IDTFs about the current error rate for improperly transmitted tracings to the physician that would indicate that it is typical for a second, senior technician to perform ''overread.'' We are proposing 0 minutes for Clinical Activity Code CA021, Line 67 on the RUC-recommended PE Spreadsheet, unless commenters can provide compelling information that a second, senior technician typically performs quality assurance measures. Otherwise, we agree with the RUC-recommended direct PE inputs and are proposing the refinements as recommended.

In addition to the proposed work RVU and direct PE input refinements, we are requesting additional information about the acquisition costs for equipment item EQ340 *Patient Worn Telemetry System.* Due to the proprietary nature of this equipment, invoices were unattainable to update this equipment item. Substantial technological improvements have been made to these devices since the last update in 2008, but they are proprietary devices, owned and manufactured for each IDTF. We are seeking public comment on the manufacturing costs and other information to help update the equipment item for CY 2022. Second, we are requesting additional information about the useful lifetime of EQ340. CMS currently assigns 3 years of useful life to EQ340, but the RUC notes that this is the only equipment item and CPT code 93228 is the only CPT code with an equipment item that has more than 500 minutes of equipment time and a useful life of 3 years or less. We are seeking public comment to help update the useful life of EQ340, as it has not been updated since 2008, and the device has experienced significant technological changes.

(32) Electrophysiologic Evaluation (CPT Code 93621)

In October 2019, the RUC identified CPT code 93621 (*Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for*

primary procedure) as a high-growth service. It is an add-on code that can be used with several different procedures—base codes or other add-on codes, diagnostic as well as therapeutic. CPT code 93621 is furnished in the facility only and thus has no direct PE inputs.

We disagree with the RUC-recommended work RVU of 1.75 based on a crosswalk to CPT code 36483 (*Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure).* We are proposing a work RVU of 1.50 based on a crosswalk to CPT code 16036 (*Escharotomy; each additional incision*). CPT code 16036 is also an add-on code for a surgical incision that shares both an identical intraservice work time and a total time of 20 minutes with CPT code 93621. While the RUC's recommended crosswalk code also has 20 minutes of intraservice and total time, CPT code 36483 is more intense than CPT code 93621, whereas CPT code 16036 has a similar level of intensity as CPT code 93621.

The RUC did not recommend and we are not proposing any direct PE inputs for CPT code 93621.

(33) Cardiac Ablation Services Bundling (CPT Codes 93653, 93654, 93655, 93656, and 93657)

The technologies and clinical practices associated with Cardiac Ablation Services have changed enough over the past decade (since 2011 when they were first developed) that the specialty societies recommended referring theses codes to CPT Editorial Panel to have the code descriptors for Cardiac Ablation Services updated to create new and more complete descriptors reflecting the fact that many of these services are commonly performed together and should be incorporated and bundled. In October 2020, the CPT Editorial Panel revised the three existing cardiac ablation codes to be bundled with 3D mapping and to include ''induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus,'' and ''left atrial pacing and recording from coronary sinus or left atrium'' and ''intracardiac echocardiography including imaging supervision and interpretation'' into their descriptors.

A survey of the Cardiac Ablation Services was sent out using the newly revised CPT code descriptors asking cardiac electrophysiologists about the revised language in the existing CPT codes. From the survey results, the RUC advisory committee believes that many of the survey respondents may not have realized that the code descriptors had been substantially revised and that they may not have read the updated code descriptors thoroughly enough to understand that services that are separately billed, were now combined into the existing codes (since CPT did not issue new codes for the revised descriptors). The RUC recommended that these services be valued as interim to allow for re-survey and subsequent review at the April 2021 RUC meeting.

CPT code 93653 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry)*(previous work RVU of 14.75 with 000-day global) is now bundled with the add-on CPT codes 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)*)(work RVU of 5.23 with 90 minutes of intraservice time) and the add-on CPT code 93621 (*Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)*)(work RVU of 2.10 with 30 minutes of intraservice time). The RUC-recommended work RVU for CPT code 93653 is 18.49, with 40 minutes of preservice evaluation, 3 minutes of preservice positioning, 15 minutes of preservice scrub/dress/wait time, 125 minutes of intraservice time and 30 minutes of immediate postservice time.

Since the two add-on codes are combined with the primary CPT code 93653, one would expect the intraservice time to have increased or remained similar to the current 180 minutes. Instead, the RUC-recommended intraservice time has decreased to 125 minutes. Accounting for changes in technologies and clinical practices from over 10 years since this code family's last review, we would expect better efficiencies and reductions in work times, but with the addition of two add-on codes whose work is mostly, if not all, added to the intraservice time, one would not expect a net decrease in minutes. This is not what the collected responses from this survey show and it is a concern. Some of CPT code 93653 add-on service times may have shifted over to the increases in preservice times, but there does appear to be a collective misunderstanding in the survey's work RVUs and physician work time responses.

In light of the RUC's intention to resurvey and re-review CPT code 93653 (and this family of codes) at the April 2021 RUC meeting, and to resolve any flaws from the initial survey, such as survey respondents probably not realizing that a new descriptor describing the inclusion of services is now bundled to the existing CPT code (and not a newly issued CPT code), we are proposing to maintain the current physician times and current work RVU of 14.75, until the AMA RUC returns with a more definitive and accurate valuation.

For CPT code 93654 (*Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed*) (work RVU of 19.75), the RUC recommends 40 minutes of preservice evaluation, 3 minutes of preservice positioning, 20 minutes of preservice scrub/dress/wait time, 240 minutes of intraservice time and 33 minutes of immediate postservice time for a total of 336 minutes, an increase to the code's current 309 total minutes. Unlike CPT codes 93653 and 93656, CPT code 93654 already accounts for the work RVUs and physician times for 3-dimensional mapping of add-on CPT code 93613. The RUC recommended maintaining the current work RVU

value of 19.75. We are proposing the RUC-recommended updates to the physician times (net increase in total minutes) and to maintain the same work RVUs for CPT code 93654 for CY 2022.

CPT code 93655 (*Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (List separately in addition to code for primary procedure)*) has a current work RVU of 7.50 with a physician intraservice time of 90 minutes. The RUC recommended a revised intraservice time of 60 minutes and 6.50 work RVUs. The primary change to CPT code 93655 is the reduction of the intraservice time of about 67 percent, which we use as a guide to determine a work RVU. We compare add-on CPT code 22854 (*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*) also with 60 minutes of intraservice and total time and a work RVU of 5.50 to CPT code 93655 and we believe that this is a more accurate valuation than the RUC's work RVU crosswalk to CPT code 34709 (*Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed, per vessel treated (List separately in addition to code for primary procedure)*) with a work RVU of 6.50 and an intraservice and total time of 60 minutes because the proportional reduction in physician time should also reflect a similar proportional reduction in work RVUs. We are proposing the RUC-recommended 60 minutes of intraservice and total time, but instead propose a work RVU of 5.50 for CPT code 93655.

CPT code 93656 (*Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and His bundle recording, when performed*) is now bundled with the add-on CPT codes 93613 (*Intracardiac electrophysiologic 3-dimensional mapping (List separately in addition to code for primary procedure)*) (work RVU of 5.23 with 90 minutes of intraservice time) and the add-on CPT code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)* (work RVU currently carrier-priced with 25 minutes of intraservice time) which previously were separately reported add-on services, similar to above CPT code 93653 and its add-on codes.

The RUC-recommended work RVU for CPT code 93656 is 20.00, with 40 minutes of preservice evaluation, 3 minutes of preservice positioning, 20 minutes of preservice scrub/dress/wait time, 210 minutes of intraservice time and 33 minutes of immediate postservice time, for a total of 306 minutes. The current physician times for CPT code 93656 are 23 minutes of preservice evaluation, 1 minutes of preservice positioning, 5 minutes of preservice scrub/dress/wait time, 240 minutes of intraservice time, and 40 minutes of immediate postservice time, for a total of 309 minutes, which is a net difference of 3 minutes less in the total proposed minutes, and the RUC is recommending a work RVU of 20.00, which is 0.23 more work RVUs than the current work RVU of 19.77.

In light of the RUC's intention to resurvey and review CPT code 93653 (and this family of codes) with its new bundling at their April 2021 RUC meeting to resolve any flaws from the initial survey, where many of the survey respondents may not have realized that the code descriptors had been substantially revised and that they may not have read the updated code descriptors thoroughly enough to respond correctly, we believe CPT code 93656 is in the same situation with its new bundling thus, we are proposing the RUC-recommended updates to the physician times (a net decrease of 3 minutes in total time) and to maintain the current work RVU of 19.77.

From the survey of CPT code 93657 (*Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (List separately in addition to code for primary procedure)*), a value of 8.00 work RVUs was obtained at the 25th percentile for this add-on code. The RUC recommended a work RVU of 6.50, for the 60 minutes of intraservice and total physician time. The current work RVU is 7.50, for 90 minutes of intraservice and total physician time.

We compare add-on CPT code 22854 (*Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)*) with 60 minutes of intraservice and total time and 5.50 work RVUs to CPT code 93657 and we believe that this is a more accurate valuation, since the primary change to CPT code 93657 is the reduction of the intraservice time of about 67 percent, which we use as a guide to determining a work RVU. The RUC-recommended work RVU is crosswalked from CPT code 34709 (*Placement of extension prosthesis(es) distal to the common iliac artery(ies) or proximal to the renal artery(ies) for endovascular repair of infrarenal abdominal aortic or iliac aneurysm, false aneurysm, dissection, penetrating ulcer, including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and treatment zone angioplasty/stenting, when performed, per vessel treated (List separately in addition to code for primary procedure)*) with a work RVU of 6.50 and an intraservice and total time of 60 minutes, does not reflect the proportional reductions to the intraservice time and work. For CPT code 93657, we are proposing the RUC-recommended 60 minutes of intraservice and total time, and a work RVU of 5.50, crosswalked from CPT code 22854. There are no direct PE inputs for these facility-only CPT codes.

(34) 3D Imaging of Cardiac Structures (CPT Codes 933X0)

In May 2020, the CPT Editorial Panel created one new add-on code to describe the 3D echocardiographic imaging and postprocessing during transesophageal or transthoracic echocardiography for congenital cardiac anomalies for the assessment of cardiac

structure(s). The 3D imaging could be performed as a follow-up to a 2D transthoracic echocardiogram.

We are proposing the RUC-recommended work RVU of 0.50 for CPT code 93XX0 (*3D echocardiographic imaging and postprocessing during transesophageal echocardiography, or during transthoracic echocardiography for congenital cardiac anomalies, for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, interatrial septum, interventricular septum) and function, when performed (List separately in addition to code for echocardiographic imaging).*

While we are proposing no refinements to the direct PE inputs, we are requesting additional information about the 3D echocardiography probe equipment item. The RUC recommended that a 3D probe was required in addition to the base echocardiography machine. We received an invoice for $31,754.30 for this equipment item. It was unclear if the invoice reflected both the 3D probe and the base echocardiography machine or only the probe itself. We are seeking additional information to know if this equipment item reflected both the 3D probe and the base echocardiography machine or only the probe.

(35) Cardiac Catheterization for Congenital Defects (CPT Codes 93X1X, 93X2X, 93X3X, 93X4X, 93X5X, and 93X6X)

In May 2020, the CPT Editorial Panel replaced a family of four cardiac catheterization codes with five new codes (CPT codes 93X1X–93X5X) to describe cardiac catheterization for congenital cardiac defect(s). The CPT Editorial Panel also replaced two cardiac output measurement codes with one new add-on code (CPT code 93X6X) to report cardiac output measurement(s), performed during cardiac catheterization for congenital cardiac defects.

We are proposing the RUC-recommended work RVU for two of the codes in this family. We are proposing a work RVU of 3.99 for CPT code 93X1X (*Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections*) and a work RVU of 6.10 for CPT code 93X2X (*Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections*) as recommended by the RUC in both cases.

For CPT code 93X3X (*Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections*), we disagree with the RUC-recommended work RVU of 6.00 and we are instead proposing a work RVU of 5.50 based on a crosswalk to CPT code 32607 (*Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral).* CPT code 32607 is a thorascopy procedure with three fewer minutes of intraservice work time (45 minutes) than CPT code 93X3X but a higher total work time of 178 minutes. CPT code 93X3X has similar surveyed work time to CPT code 93X1X but the RUC recommended a work RVU of 3.99 for the first code in the family as compared to 6.00 for CPT code 93X3X. While we agree that CPT code 93X3X is a more intensive procedure, we do not agree that it should be valued more than two full RVUs higher as compared to the first code in the family. We believe that it would be more accurate to propose a work RVU of 5.50 based on the aforementioned crosswalk to CPT code 32607. We note that the intensity of CPT code 93X3X remains higher than the first two codes in the family at the proposed work RVU of 5.50.

For CPT code 93X4X (*Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections),* we disagree with the RUC-recommended work RVU of 7.91 and we are instead proposing a work RVU of 6.84 based on a crosswalk to CPT code 32608 (*Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral).* CPT code 32608 is another thorascopy procedure from the same family as CPT code 32607, with the same 60 minutes of intraservice work time as CPT code 93X4X and a higher total work time of 195 minutes. In the same fashion as the previous code, CPT code 93X4X has similar surveyed work time to CPT code 93X2X but the RUC recommended a work RVU of 6.10 for the second code in the family as compared to 7.91 for CPT code 93X4X. While we agree that CPT code 93X4X is a more intensive procedure, we do not agree that it should be valued almost two full RVUs higher as compared to the second code in the family. We believe that it would be more accurate to propose a work RVU of 6.84 based on the aforementioned crosswalk to CPT code 32608. We note that the intensity of CPT code 93X4X remains the highest among the first four codes in the family at the proposed work RVU of 6.84. We believe that our proposed RVUs for CPT codes 93X3X and 93X4X better preserve relativity both within the family and also with other services on the PFS.

For CPT code 93X5X (*Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections),* we disagree with the RUC-recommended work RVU of 9.99 and we are instead proposing a work RVU of 8.88 based on the median work RVU from the survey. The RUC's recommendation of a work RVU of 9.99, based on maintaining the prior work RVU of deleted CPT code 93532 (*Combined right heart catheterization and transseptal left heart catheterization through intact septum with or without retrograde left heart catheterization, for congenital cardiac anomalies*), was nearly equal to the 75th percentile work RVU from the survey at 10.00. Since the RUC recommended the survey median work RVU for the other four non-measurement codes in the family, we do not understand the recommendation of a value for CPT code 93X5X that sits within 0.01 RVUs of the survey 75th percentile. The survey for CPT code 93X5X also revealed that it typically requires far less work time to perform as compared with predecessor code 93532 (83 minutes of intraservice work time as compared to 175 minutes for the predecessor code). Although we agree that CPT code 93X5X is a more intensive procedure than its predecessor code, we do not believe that the work RVU should remain unchanged given the greatly reduced work time in the new procedure. Since the two components of work are time and intensity, we believe that decreases in time should typically be reflected in decreases to work RVUs. We are therefore proposing a work RVU of 8.88 for CPT code 93X5X based on the survey median outcome. We believe that our proposed RVU more accurately accounts for these changes in surveyed work time and better preserves relativity with the rest of the family.

For CPT code 93X6X (*Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects*), we disagree with the RUC-recommended work RVU of 1.75 and we are instead proposing a work RVU of 1.44 based on a crosswalk

to CPT code 37253 (*Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel*). CPT code 37253 is an intravascular ultrasound procedure that shares the same intraservice work time of 20 minutes as CPT code 93X6X and has 1 additional minute of immediate postservice time. We note that the intensity of CPT code 93X6X as recommended by the RUC at a work RVU of 1.75 would be the second-highest in the family, higher than CPT code 93X5X for example. We do not agree that this cardiac output measurement code would typically be more intensive to perform than the two types of heart catheterization taking place in CPT code 93X5X.

We also note that the recommended work RVU for CPT code 93X6X was higher than the sum of its two predecessor codes. Former CPT codes 93561 (*Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; with cardiac output measurement*) and 93562 (*Indicator dilution studies such as dye or thermodilution, including arterial and/or venous catheterization; subsequent measurement of cardiac output*) had CY 2021 work RVUs of 0.95 and 0.77 respectively. These two codes sum together to a work RVU of 1.72 which would be lower than the RUC's recommendation of 1.75 for CPT code 93X6X. The RUC's recommendation suggests that there would be no efficiencies gained or savings created in the process of creating CPT code 93X6X; we believe that the survey for the new code indicates otherwise, as the predecessor codes had work times of 15 minutes and 12 minutes respectively (27 minutes total) as compared to 20 minutes of surveyed work time for the new code. This lower work time suggests that the creation of CPT code 93X6X has led to greater efficiencies in the service which, under the resource-based nature of the RVU system, lends further support for a reduction in the work RVU as compared to a sum of the predecessor codes. We therefore believe that it would be more accurate to propose a work RVU of 1.44 based on the aforementioned crosswalk to CPT code 37253.

The RUC did not recommend any direct PE inputs for these six codes and we are not proposing any direct PE inputs.

(36) Outpatient Pulmonary Rehabilitation Services (CPT Codes 946X1 and 946X2)

CPT code 946X1 (*Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)*) and CPT code 946X2 (*Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session) (Do not report 946X1, 946X2 in conjunction with 94760, 94761)*) are two new codes created by the CPT Editorial Panel to take the place of the HCPCS G-code G0424 (*Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day*) which was created in 2010. The RUC recommended work RVUs for CPT codes 946X1 and 946X2 of 0.55 and 0.69 respectively. We disagree with the RUC-recommended work RVUs for both CPT code 946X1 and 946X2. Although the pulmonary rehab service as described by these new codes have not changed, the RUC recommendation included an increase in intraservice and total time for the services. As the survey time increased for the pulmonary rehabilitation codes, an increase in work value may be appropriate.

Based on a comparison of intraservice time for the current code relative the recommended values, we are proposing a work RVU of 0.36 for CPT code 946X1 and a work RVU of 0.56 for CPT code 946X2, which is an increase to the work RVU from the HCPCS G-code G0424 that these two codes are replacing and reflects a commensurate increase in work relative to the increase in intraservice time.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Provide education/obtain consent'' (CA011) activity from the RUC-recommended 15 minutes to 2 minutes for both CPT codes 946X1 and 946X2. The recommended materials for this code family state that the 15 minutes for the CA011 activity are used for education which is an integral component of pulmonary rehabilitation programs. There is education provided at each separate session following a curriculum outlined in the guideline and covers both educational topics concerning self-management and educational topics concerning advance care planning which is different at every session.

We do not agree that it would be typical for CPT codes 946X1 and 946X2 to require an additional 13 minutes for education and consent given the patient is seen two to three times a week for pulmonary rehabilitation and the education can be covered during those sessions. We are refining the clinical labor time to 2 minutes for both CPT codes 946X1 and 946X2 to maintain relativity, particularly in light of the clinical similarities between these services. The education would be done during the ''Perform procedure/service—NOT directly related to physician work time'' (CA021), as stated above, as the patient is seen two to three times a week for pulmonary rehabilitation.

We are also proposing to refine the equipment time and lower the pulse oximeter w-printer (EQ211) and exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board) (EQ118) equipment times from 93 minutes to 80 minutes to match this change in clinical labor time for CPT codes 946X1 and 946X2.

Additionally, we are proposing to revise the utilization that we would use to set rates for CPT code 946X2 to reflect our understanding that pulmonary rehabilitation is always done with pulse oximetry. Thus, we are proposing to update our analytic crosswalk to reflect our belief that 100 percent of the utilization for the pulmonary rehabilitation services currently billed using HCPCS code G0424 will now be billed using CPT code 946X2. We believe that it is unlikely that these services would typically be billed using CPT code 946X1 since it is our understanding that pulmonary rehabilitation is typically provided with pulse oximetry, and therefore, we expect little to no utilization for CPT code 946X1. We are seeking comment from stakeholders on our understanding and proposal to revise the utilization as stated.

(37) Remote Therapeutic Monitoring (CPT Codes 989X1, 989X2, 989X3, 989X4, and 989X5)

Remote Therapeutic Monitoring (RTM) is a family of five codes created by the CPT Editorial Panel in October 2020 and valued by the RUC at its January 2021 meeting. The RTM family includes three PE-only codes and two codes that include professional work.

In recent years, we have finalized seven codes in the Remote Physiological Monitoring (RPM) family that include services similar to the new RTM codes. (See the CY 2021 PFS final rule at 85 FR 84542 through 84546 for more information.) Based upon our analysis, the services and code structure of RTM resemble those of RPM. For example, the RTM codes reflect similar staff and

physician work, although the specific equipment used is different.

While there are notable similarities between the two sets of code descriptors, there are two primary differences. One difference is that according to RUC documents, primary billers of RTM codes are projected to be nurses and physical therapists. Stakeholders have suggested that the new RTM coding was created to allow practitioners who cannot bill RPM codes to furnish and bill for services that look similar to those of RPM. RPM services are considered to be E/M services and physical therapists, for example, are practitioners who cannot bill E/M services. The RTM codes, instead, are general medicine codes.

In our review of the new codes, we identified an issue that disallows physical therapists and other practitioners, who are not physicians or NPPs, to bill the RTM codes. By modeling the new RTM codes on the RPM codes, ''incident to'' services became part of the three direct practice expense-only (PE-only) codes (that is, CPT codes 989X1, 989X2, and 989X3) as well as the two professional work codes (that is, CPT codes 989X4 and 989X5). As a result, the RTM codes as constructed currently cannot be billed by, for example, physical therapists. We describe ''incident to'' services in the CMS Medicare Benefit Policy Manual, Chapter 15, beginning at section 60 and note that only physicians and certain other practitioners are authorized to furnish and bill ''incident to'' services. Incident to services are:

- An integral, although incidental, part of the physician's professional service (see § 60.1);
- Commonly rendered without charge or included in the physician's bill (see § 60.1A);
- Of a type that are commonly furnished in physician's offices or clinics (see § 60.1A); and
- Furnished by the physician or by auxiliary personnel under the physician's direct supervision (see § 60.1B).

Additionally, we designated the treatment management RPM codes (that is, CPT codes 99457 and 99458) as care management services (84 FR 62697 through 62698), which allow general supervision rather than direct supervision for incident to services. The treatment management RTM codes (CPT codes 989X4 and 989X5), because they are not E/M codes, cannot be designated as care management services. As a result, we are seeking comment on how we might remedy the issues related to the RTM code construction in order to permit practitioners who are not physicians or NPPs to bill the RTM codes.

The second primary difference between the RTM and RPM codes is the nature of the data to be collected and how it is collected. According to the code descriptors, RTM codes monitor health conditions, including musculoskeletal system status, respiratory system status, therapy (medication) adherence, and therapy (medication) response, and as such, allow non-physiologic data to be collected. Reportedly, data also can be self-reported as well as digitally uploaded. RPM requires that data be physiologic and be digitally uploaded. We note that, for both sets of codes, the device used must meet the FDA definition of a medical device as described in section 201(h) of the Federal Food, Drug and Cosmetic Act (FFDCA). We are seeking comment on the typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors (for example, respiratory system status, musculoskeletal status, medication adherence, pain) for the RTM services.

For CY 2022, we are proposing the RUC-recommended work RVU of 0.62 for CPT code 989X4 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes*) and the RUC-recommended work RVU of 0.61 for its add-on code, CPT code 989X5 (*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*) as a means of maintaining parity with the two RPM treatment management codes (CPT codes 99457 and 99458) upon which the two RTM codes are based. We also are proposing the RUC-recommended direct PE inputs for the two treatment management codes, CPT codes 989X4 and 989X5, without refinement.

We are proposing to refine the direct PE inputs for the three PE-only codes: CPT code 989X1 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment*), CPT code 989X2 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*), and CPT code 989X3 (*Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*). We are proposing to value the PE for CPT code 989X1 by crosswalking to the PE RVU for RPM code 99453 upon which the new RTM code was based. We also are proposing to value the PE for CPT codes 989X2 and 989X3 by crosswalking to the PE RVU for comparable RPM code 99454, a code that includes payment for the medical device used to collect and transmit data. We note that the only input to CPT code 989X2 is a monthly fee of $25, which would not be paid as a direct cost under the PFS. Historically, we have considered most computer software and associated licensing fees to be indirect costs. However, as we noted in section II.B. of this proposed rule (the PE section), stakeholders have routinely expressed concerns with this policy, especially for evolving technologies that rely primarily on software and licensing fees with minimal costs in equipment or hardware.

(38) Principal Care Management and Chronic Care Management (CPT Codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25)

In recent years, we have engaged in efforts to update and improve the relative value of care management and coordination services within the PFS by identifying gaps in payment and coding. One of those PFS services is Chronic Care Management (CCM). CCM services, which include management and support services provided by clinical staff under the supervision of a physician or NPP or services provided personally by a physician or NPP, have received ongoing refinements related to payment and coding since CY 2013.

Beginning in the CY 2014 PFS final rule (78 FR 74414 through 74427), we noted that physicians and NPPs who furnish care to patients with multiple chronic conditions require greater resources than are required to support patient care in a typical E/M service. In response, we finalized a separately payable HCPCS code, GXXX1 (*Chronic Care Management (CCM) services*

furnished to patients with multiple (2 or more) chronic condition expected to last at least 12 months, or until the death of the patient; 20 minutes or more per in 30 days of chronic care management services provided by clinical staff and directed by a physician or other qualified health care practitioner). For CY 2015 (79 FR 67715 through 67730), we refined aspects of the existing CCM policies and adopted separate payment for CCM services under CPT code 99490 (*Chronic care management services (CCM), at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; Chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline; Comprehensive care plan established, implemented, revised, or monitored*). For CY 2017 (81 FR 80244), we adopted CPT codes 99487 (*Complex chronic care management (CCCM) services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) and 99489 (*Complex chronic care management (CCCM) services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). Then, in the CY 2019 PFS final rule (83 FR 59577), we adopted a new CPT code, 99491 (*Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*), to describe at least 30 minutes of CCM services performed personally by a physician or NPP. In the CY 2020 PFS final rule (84 FR 62690), we established payment for an add-on code to CPT code 99490 by creating HCPCS code G2058 (*Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month*). We also created two new HCPCS G codes, G2064 and G2065 (84 FR 62692 through 62694), representing comprehensive services for a single high-risk disease (that is, principal care management). In the CY 2021 PFS final rule (85 FR 84639), we finalized a RUC-recommended replacement code for HCPCS code G2058, CPT code 99439, which was given the same valuation and the identical descriptor as G2058.

For CY 2022, the RUC resurveyed the CCM code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes: 99X21 (*Chronic care management services each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*), 99X22 (*Principal care management services for a single high-risk disease first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*), 99X23 (*Principal care management services for a single high-risk disease each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure),* 99X24 (*Principal care management services, for a single high-risk disease first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*), and 99X25 (*Principal care management services, for a single high-risk disease each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). The CCM/CCCM/PCM code family now includes five sets of codes, each set with a base code and an add-on code. The sets vary by the degree of complexity of care (that is, CCM, CCCM, or PCM), who furnishes the care (that is, clinical staff or the physician or NPP), and the time allocated for the services. The RUC-recommended values for work RVUs and direct PE inputs for CY 2022 derive from the recent RUC specialty society survey (see Table 12).

We reviewed the RUC-recommended values for the 10 codes in the CCM family and are proposing to accept the recommended work values for the codes. We are proposing the RUC-recommended direct PE inputs without refinements. We believe that proposing to accept these updated values is consistent with our goals of ensuring continued and consistent access to these crucial care management services and acknowledges our longstanding concern about undervaluation of care management under the PFS. We are seeking comment, however, on whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate.

In addition to the proposals on the values for CCM codes, we are interested in understanding more about the standard practice used by practitioners to obtain beneficiary consent for these services. We have received questions from stakeholders regarding the consent requirements for CCM services. We believe that these questions have arisen because of the many flexibilities allowed in response to the PHE for COVID–19. In particular, during the PHE for COVID–19, we allowed stakeholders to obtain beneficiary consent for certain services under general supervision (85 FR 19230, April 6, 2020). Before the PHE for COVID–19, we required that beneficiary consent be obtained either by or under the direct supervision of the primary care practitioner. This requirement is consistent with the conditions of payment for this service under the PFS. As we consider what policies implemented during the PHE for COVID–19 should remain in effect beyond the PHE, we are interested in understanding how billing practitioners furnishing CCM at different service sites (for example, physician office settings, RHCs, FQHCs) have been obtaining beneficiary consent over the past year and how different levels of supervision impact this activity. We welcome public comment on the issue, specifically on what levels of supervision are necessary to obtain beneficiary consent when furnishing CCM services and will

consider such comments in future rulemaking.

We also are proposing to adopt CPT codes 99X22 (*PCM First 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*) and 99X24 (*PCM First 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month*) to replace HCPCS codes G2064 and G2065 in the calculation of the rate for HCPCS code G0511 for General Care Management services billed by RHCs and FQHCs. The payment rate for HCPCS code G0511 is calculated based on the average of the national non-facility PFS payment rate for care management and general behavioral health integration codes (CPT codes 99484, 99487, 99490, and 99491) as well as HCPCS codes G2064 and G2065 which describe PCM services billed under the PFS. The payment rate for HCPCS code G0511 is updated annually based on the PFS amounts for these codes.

TABLE 12: CY 2022 CCM/CCCM/PCM Proposed Values

CPT Code	Short Descriptor	Current Work RVU	RUC-recommended Work RVU	CMS Proposed Work RVU
99490	CCM clinical staff first 20 min	0.61	1.00	1.00
99439	CCM clinical staff each add 20 min	0.54	0.70	0.70
99491	CCM physician or NPP work first 30 min	1.45	1.50	1.50
99X21	CCM physician or NPP work each add 30 min	new	1.00	1.00
99487	CCCM clinical staff first 60 min	1.00	1.81	1.81
99489	CCCM clinical staff each add 30 min	0.50	1.00	1.00
99X22 (currently G2064)	PCM physician or NPP work first 30 min	new	1.45	1.45
99X23	PCM physician or NPP work each add 30 min	new	1.00	1.00
99X24 (currently G2065)	PCM clinical staff first 30 min	new	1.00	1.00
99X25	PCM clinical staff each additional 30 min	new	0.71	0.71

(39) Moderate Sedation (HCPCS code G0500)

(39) Moderate Sedation (HCPCS Code G0500)

Following the publication of the CY 2021 PFS final rule, a stakeholder contacted us regarding what they believed to be an error in the intraservice work time for HCPCS code G0500 (*Moderate sedation services provided by the same physician or other qualified health care professional performing a gastrointestinal endoscopic service that sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intra-service time; patient age 5 years or older (additional time may be reported with 99153, as appropriate)*). We established HCPCS code G0500 in CY 2017 to more accurately capture the work of administering moderate sedation for gastrointestinal endoscopic procedures for patients 5 years of age or older. We based the physician work and time for HCPCS code G0500 on data from the 100 gastroenterologists who completed the survey of CPT code 99152 (*Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older*) presented at the October 2015 RUC meeting. The survey data for CPT code 99152 showed a significant bimodal distribution with data from gastroenterologists performing endoscopic procedures demonstrating a markedly different and lesser amount of physician work for moderate sedation compared to other specialties. The stakeholder stated that the finalization of 12 minutes of intraservice work time for HCPCS G0500 appeared to be an error and asked CMS to correct it to reflect the 5 minutes of intraservice work time indicated by survey data when gastroenterologists performed endoscopic procedures.

While we appreciate the feedback from the stakeholder, we disagree that the finalization of 12 minutes of intraservice work time for HCPCS code G0500 (matching CPT code 99152) was an error. The work time for HCPCS code G0500 was proposed and finalized at 12 minutes in CY 2017, with the intention that it would match the work time for CPT code 99152. This was the rationale behind the descriptor for HCPCS code G0500 listing that the code was intended for the initial 15 minutes of intraservice time. Furthermore, several commenters questioned the work time for HCPCS code G0500 in the CY 2017 PFS final rule (81 FR 80341) and we stated in response that we expected that practitioners would report the appropriate CPT or HCPCS code that most accurately described the services performed during a patient encounter, including those services performed concurrently and in support of a procedural service consistent with CPT guidance. We noted that the commenters referred to the time for moderate sedation in the survey data, while the time thresholds for the moderate sedation codes were intended to match the intraservice time of the procedure itself. For a full discussion of this topic, we refer readers to the CY

2017 PFS final rule (81 FR 80339 through 80349).

Although we are not proposing a change in the work time for HCPCS code G0500, we are soliciting comments on this issue in the interest of gaining additional information about the typical use of this procedure.

(40) Payment for Synthetic Skin Substitutes (HCPCS Codes GXXAB, GXXAC, GXXAD, GXXAE, GXXAF, GXXAG, GXXAH, and GXXAI)

On July 1, 2020, Medicare implemented HCPCS code C1849 (*Skin substitute, synthetic, resorbable, per square centimeter*) and made it payable under the OPPS. In the CY 2021 OPPS final rule (85 FR 86064 through 86067) Medicare finalized payment for C1849—and the associated synthetic skin substitute products—allowing it to be billed with graft skin substitute procedure CPT codes 15271 through 15278. We note that under the OPPS, payment for C1849 is packaged into the payment for the graft skin substitute procedure, and its costs are reflected in the development of the payment rates for those services. The creation of the C-code and the CY 2021 OPPS rulemaking addressed the need for a mechanism to pay for graft skin substitute application services performed with synthetic graft substitute products in the outpatient hospital setting, which is comparable to how Medicare pays for graft skin substitute application services performed with graft skin substitutes that are regulated by the Food and Drug Administration (FDA) under its regulatory framework at section 361 of the Public Health Service (PHS) Act for human cells, tissues, and cellular and tissue-based products (HCT/Ps). We want to clarify that the availability of a HCPCS code for a particular HCT/P does not mean that the product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271 (85 FR 86058). We note that in a response to the CY 2021 OPPS proposal, a commenter noted that the use of a C-code meant that synthetic graft skin substitute products would only be payable under the OPPS, and would not be able to be reported for graft skin substitute services using a synthetic product in the physician office setting (85 FR 86066).

Currently, graft skin substitute application services are paid separately from the (HCT/Ps) skin substitutes under the PFS. Specifically, when a physician or NPP furnishes a surgical service to apply a (HCT/Ps) skin substitute in a non-facility setting, they may bill Medicare for the surgical service (as described by CPT codes 15271 through 15278), and separately bill for the (HCT/Ps) skin substitute. For CY 2022, in order to reconcile the gap in payment for synthetic products in the physician office setting, we are proposing to create eight HCPCS codes (parallel to the aforementioned existing surgical codes) that would include the synthetic graft skin substitute product as a supply cost in determining the PFS rate. We believe that it would be appropriate to consider these products as incident to supplies in the office setting, and as such they should be built in as a supply cost in calculating the PFS rate. Therefore, we are proposing to consider these products as incident to supplies in the office setting.

The codes and long descriptors for the proposed synthetic graft skin substitute services are:

- HCPCS Code GXXAB: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area.*
- HCPCS Code GXXAC: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure).*
- HCPCS Code GXXAD: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children.*
- HCPCS Code GXXAE: *Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure).*
- HCPCS Code GXXAF: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area.*
- HCPCS Code GXXAG: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure).*
- HCPCS Code GXXAH: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children.*
- HCPCS Code GXXAI: *Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure).*

We are proposing contractor pricing for these codes for CY 2022; we note that there is limited data available on the cost of synthetic skin substitute products in physician offices, so we are also seeking comment and documentation regarding the appropriate values for these services for consideration of national pricing in future rulemaking.

Though we are proposing contractor pricing in the interim, we also considered an alternative approach that would use crosswalks to value these services in the physician office setting in a way that is commensurate with the rates paid under the OPPS. Though limited data exists on the cost of graft synthetic skin substitute products in physician offices, hospitals began reporting costs associated with synthetic skin substitute products in CY 2020 after C1849 became effective and payable under the OPPS starting in July, 2020. We analyzed CY 2020 OPPS claims data and estimate hospital outpatient department costs for graft synthetic skin substitute products averaged $1,500. We note that under the OPPS, outpatient departments are paid separately for the primary surgical application codes (CPT codes 15271, 15273, 15275, 15277), and the costs associated with the synthetic products

as well as the add-on services (described by CPT codes 15272, 15274, 15276, 15278) are packaged into the payment for the primary procedure.

Under this alternative, we considered following an approach similar to that under the OPPS where the cost of the supply would be included in the primary codes (described by HCPCS GXXAB, GXXAD, GXXAF, and GXXAH) and not the add-on codes (described by HCPCS GXXAC, GXXAE, GXXAG, and GXXAI), though the add-on would continue to be reported and paid separately. Specifically, we would use direct crosswalks for the work RVUs, MP RVUs, and facility PE RVUs from the current surgical application codes (that is, CPT codes 15271 through 15278) as we believe that these payment components for the synthetic graft skin substitute services, described by the aforementioned HCPCS codes, would be similar.

However, with regards to the non-facility PE RVUs, we recognize that there are significant supply costs associated with synthetic skin substitute products. As described previously, we estimate that hospitals face average costs associated with synthetic skin substitute products of $1,500. We note that the PE methodology, which relies on the allocation of indirect costs based on the magnitude of direct costs, may not be appropriate for these types of services because the specialists that typically furnish these types of services do not typically have significant supply costs within the methodology. As such, we used the hospital reported costs and we looked to other codes where specialists frequently have similarly high supply costs in order to crosswalk the non-facility PE RVUs. We considered services that have a significant proportion of supply costs and are furnished by specialists who typically have higher supply costs as potential crosswalks for the non-facility PE RVUs. For example, we considered a crosswalk to CPT code 21461 (*Open treatment of mandibular fracture; without interdental fixation*) for HCPCS codes GXXAB and GXXAF, and a crosswalk to CPT code 21462 (*Open treatment of mandibular fracture; with interdental fixation*) for HCPCS codes GXXAD and GXXAH. As an estimate of non-facility PE, we believe these would be appropriate codes for crosswalking non-facility PE RVUs. As previously discussed, for the purposes of the work RVUs, MP RVUs, and facility PE RVUs, we believe direct crosswalks to the current surgical application codes would be appropriate as those values would generally not be impacted by the addition of a synthetic skin substitute product. We realize this alternative considered would follow a similar coding and payment approach established under the OPPS, and that potential adoption of this alternative would mean that the cost of the products is included in the primary codes and not included in the add-on codes. We welcome feedback on our proposal to treat synthetic skin substitute products as incident to supplies in the physician office, the proposal to have contractor pricing for these codes, and other ways we could obtain detailed and reliable cost information on synthetic skin substitutes that are furnished in the non-facility setting. We are also seeking comment on the alternative approach that we considered (using crosswalks to value these services in the physician office setting). Additionally, we are seeking comment on potential ways to reconcile these coding and payment differences across settings to yield a more consistent and rational payment approach for synthetic and HCT/P graft skin substitutes.

(41) External Extended ECG Monitoring (CPT Codes 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248)

In the CY 2021 PFS proposed rule (85 FR 50164), we proposed to adopt the RUC recommendations for CPT codes 93241 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93242 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93244 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*), 93245 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*), 93246 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93247 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*), and 93248 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation*).

We noted that the recommendations for this family of codes contain one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item. Instead we received pricing information from two sources: A weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing the total costs of the health care provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Stakeholders also submitted a series of invoices from the clinical study marketplace with a price of $595, which we rejected as we typically require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item.

After consideration of the information, we proposed to employ a crosswalk to an existing supply for use as a proxy price until we received pricing information to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We proposed to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24. We believed the kit to be the closest match from a pricing perspective to employ as a proxy until we would be able to arrive at an invoice that is representative of commercial market pricing. We welcomed the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply. In response to our proposal, we received conflicting information from commenters and in the CY 2021 PFS final rule (85 FR 84631), we ultimately finalized contractor pricing for CY 2021 for the four codes that include this supply input (CPT codes 93241, 93243, 93245, and 93247) to allow additional time to receive more pricing information.

We note that stakeholders have continued to engage with CMS and the MACs on payment for this service. We remain concerned that we continue to hear that the supply costs as initially considered in our CY 2021 PFS proposal are much higher than they should be. At the same time we also have heard that

the resource costs, as reflected in the contractor based payments do not adequately cover the incurred cost for the SD339 supply that is used to furnish these services. In consideration of continued access to these services for Medicare beneficiaries, we are once again seeking public comment and information to support CMS' future rulemaking to establish a uniform national payment that appropriately reflects the PE that are used to furnish these services. As previously stated, invoices or other additional information, including for example, which proxy supply items could be used to establish cost for the SD339 supply, information on use/application and potential alternatives (as appropriate) to the supply items, would be ideal for us to use in establishing fair and stable pricing for these services. We note that in the absence of such additional and actionable information (that is, information that provides further context to information that has already been considered) we are proposing to maintain contractor pricing for these services.

(42) Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

During the PHE for COVID–19, several stakeholders have contacted CMS with concerns about the additional costs borne by physician and NPPs due to the pandemic that may impact the professional services furnished to Medicare beneficiaries. For example, we have heard from stakeholders about higher costs due to additional supplies, such as personal protective equipment, and increased time that physicians, NPPs and their clinical staff may spend with patients to mitigate further spread of infection when, for example, stakeholders are working to rule out a COVID–19 infection, or furnishing other services to a patient with a confirmed COVID–19 infection. While costs such as these may diffuse into Medicare payment rates over a period of time, our payment systems, including the PFS, are not generally designed to accommodate more acute increases in resource costs, even if they are widespread. We acknowledge the circumstances stakeholders have identified that may lead to additional costs borne by physicians and NPPs during the PHE, and we have developed and implemented policies, as appropriate and where possible, to maintain beneficiary access to necessary services during the PHE. CMS is continuing to think broadly about the concerns raised, and specifically about the types of resource costs that may not be fully reflected in payment rates for existing services, or costs that could be accounted for by establishing new payment rates for new services. We are interested in feedback from stakeholders about additional strategies to account for PHE-related costs, including feedback on the specific types of services and costs that may benefit from further review, such as infectious disease control measures, research-related activities and services, or PHE-related preventive or therapeutic counseling services. We are interested in detailed feedback from stakeholders to help inform whether we should consider making changes to payments for services or develop separate payments for such services in future rulemaking.

(43) Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management

Adequate treatment of pain is a significant public health challenge. Centers for Disease Control and Prevention (CDC) data indicate 50 million adults in the United States have chronic daily pain, with nearly 20 million experiencing high impact pain that interferes with daily life or work. Pain is the most common reason individuals seek medical care, and more than 20 percent of office visits are associated with pain.[4] In the United States, 42.6 percent of adults report having pain on some days in the past 6 months,[5] and chronic pain and high-impact chronic pain are experienced by 20.4 percent and 8 percent of adults, respectively.[6] The high prevalence of pain exacts a substantial economic toll: Medical expenditures and lost productivity related to pain result in a cost to the United States estimated at up to $635 billion.[7]

In 2010, HHS, through the National Institutes of Health (NIH), contracted with the Institute of Medicine to make recommendations ''to increase the recognition of pain as a significant public health problem in the United States.'' In its 2011 report entitled *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research,* the Institute of Medicine, through a study mandated by Congress, recommended significant improvements in pain prevention, care, education, and research and development of a population health-level strategy to address pain care.[8] The report described that the unique experience of pain requires a combination of person-centered therapies and coping techniques influenced by genes, cultural attitudes, stress, depression, ability to understand health information, and other behavioral, cultural, and emotional factors. It noted that individualized care can require adequate extra time to counsel patients and caregivers, promote self-management, and consult with other providers, but current reimbursement systems are not designed to efficiently pay for this approach. HHS subsequently convened an expert committee to oversee creation of the *National Pain Strategy* (NPS), issued in 2016.[9] The NPS addressed six key areas of care: Population research, prevention and care, disparities, service delivery and payment, professional education and training, and public education/communication. In this report, NPS' vision is to ''decrease the prevalence of pain across its continuum from acute to high-impact chronic pain and its associated morbidity and disability across the lifespan,'' and aim ''to reduce the burden of pain for individuals, their families, and society as a whole.''

This work was followed by HHS's 2019 release of its *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations (PMTF Report).*[10] The PMTF Report focuses on the development of patient-centered pain treatment plans to establish diagnosis and set measurable outcomes such as improvements in quality of life, function, and activities of daily living. It emphasized multi-modal, multi-disciplinary approaches that include various modalities for acute and chronic pain. The PMTF Report also identified five broad treatment categories: Medications including opioids and non-opioids, restorative therapies, interventional approaches, behavioral approaches, and complementary and integrative health. It stressed the importance of special populations including older adults and persons with

[4] Daubresse M, Chang HY, Yu Y, Viswanathan S, Shah ND, Stafford RS, Kruszewski SP, Alexander GC. Ambulatory diagnosis and treatment of non-malignant pain in the United States, 2000–2010. Medical care. 2013 Oct;51(10).

[5] *Erratum:* Vol. 66, No. 29. MMWR Morb Mortal Wkly Rep 2017;66:1238. DOI: *http://dx.doi.org/10.15585/mmwr.mm6644a10external* icon.

[6] Dahlhamer J, Lucas J, Zelaya, C, et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:1001–1006. DOI: *http://dx.doi.org/10.15585/mmwr.mm6736a2.*

[7] Gaskin DJ, Richard P. The economic costs of pain in the United States. The Journal of Pain. 2012 Aug 1;13(8):715–24.

[8] *https://www.nap.edu/catalog/13172/relieving-pain-in-america-a-blueprint-for-transforming-prevention-care.*

[9] *https://www.iprcc.nih.gov/national-pain-strategy-overview/national-pain-strategy-report.*

[10] *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

relapsing conditions, Veterans, and people who receive palliative care. The PMTF Report recognized the importance of proper opioid stewardship for individuals who need opioids to effectively manage their pain. As the Task Force noted, there are ongoing concerns regarding suicide and suicidal ideation due to pain, and a lack of access to pain treatment, including appropriate access to opioid medications. The PMTF Report noted that management of pain conditions often requires multidisciplinary coordination among health care professionals, and that the experience of pain can intensify other health issues such as delayed recovery from surgery, or exacerbate behavioral health conditions. Many health care professionals, including primary care providers, have opted out entirely in treating pain, worsening an existing shortage of pain specialists and making chronic pain care hard to access, including for people who frequently experience disparities in pain care such as rural dwellers, racial/ethnic minorities, and people with disabilities. The COVID–19 Public Health Emergency has also had an impact on the ability of many older adults and people with disabilities' access to care, although telehealth modalities have shown promise in broadening access to services and supports.

At the same time individuals are experiencing difficulties finding pain care, the country is also coping with a worsening opioid and SUD crisis. The current environment involves shifting ''waves'' of overdose deaths associated with heroin, synthetic opioids, and prescription drugs, and intensifying stimulant and polysubstance use. Preliminary Centers for Disease Control and Prevention data released in April 2021 show a 29 percent rise in overdose deaths from October 2019 through September 2020—the most recent data available—compared with the previous 12-month period.[11] Illicitly manufactured fentanyl and other synthetic opioids were the primary drivers, although many fatal overdoses have also involved stimulant drugs, particularly methamphetamine. In December 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) released a preliminary report from its Drug Abuse Warning Network, which captures data on emergency department (ED) visits related to recent substance use and misuse such as alcohol use, illicit drug use, suicide attempts, and nonmedical use of pharmaceuticals. Most commonly associated with ED visits in the participating hospitals are illicit substances and central nervous system agents. Among illicit drugs, stimulants (including methamphetamine and illicit amphetamine) are the most common, followed by cannabinoids (including marijuana and synthetic cannabinoids).[12]

The PMTF Report urged clinicians to use a comprehensive, individualized, person-centered approach to the diagnosis and treatment of pain featuring multiple therapeutic modalities. The uptake of this approach is an urgent concern as growing numbers of older adults are enrolling in Medicare. Some estimates indicate about half of older adults have pain that interferes with function. Primary care clinicians and specialists are already facing challenges in treating pain and associated chronic disease in the Medicare population, where conditions such as arthritis, bone/joint disorders, back and neck pain, cancer and other conditions that inform and at times inhibit employing the full spectrum of pain management therapies are common. We believe untreated and inappropriately treated pain may translate to increased costs to the Medicare program as more beneficiaries experience functional decline, incapacitation, and frailty. Additional risks in untreated pain include individuals using illicit drugs such as cannabis; inadequate treatment of mental disorders such as depression and anxiety, misuse of prescription drugs, alcohol and other drug use disorder, and increased suicide risk and suicide.

In 2019 HHS issued the *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics* (the Guide) to support the thoughtful, deliberative, and measured discontinuation of long-term opioid analgesics, and mitigate harm and risk to patients who are working with their clinicians to undergo appropriate tapering or discontinuation.[13] The Guide notes that decisions to continue or reduce opioid medications for pain should be collaborative and based on the individual patient's goals and circumstances and clinicians should consider, for example, whether opioid medications continue to support patients meeting treatment goals; if opioids are exposing the person to an increased risk for serious adverse events or an opioid use disorder; and whether benefits continue to outweigh risks of opioids. Whether or not opioids are used in treatment, safe and effective non-opioid treatments can be integrated into patients' pain management plans based on an individualized assessment of benefits and risks, and considering the patient's diagnosis, goals and circumstances.[14] Unique needs and coordination across the health care team is critical and clinicians and care teams have a responsibility to provide, or arrange for, coordinated management of patients' pain including any medication-related issues. The system of care should not ultimately result in patient abandonment. The FDA issued a safety announcement in 2019, advising that health care professionals should not abruptly discontinue opioids in patients who are physically dependent and that patient-specific plans should be created to gradually taper off opioids, in part due to the risk of adverse events including abrupt withdrawal symptoms, increased pain, mood changes, mental health impact, psychosocial impact, and importantly, suicide risk.[15]

In 2020 the National Academy of Medicine, as part of its ''Action Collaborative to Countering the U.S. Opioid Epidemic,'' began an effort to understand more about the state of chronic pain management, and to bring greater awareness to any intended and unintended consequences of opioid prescribing metrics as they pertain to the delivery, access, and coordination of chronic pain management and care. CMS is one of the sponsors of this work. The aim of this project is to visually illustrate the chronic pain management journey and accelerate the uptake of a range of pain treatments by outlining approaches to effective communication that leads to strong clinical relationships and optimal quality of life for people with pain.[16]

The SUPPORT Act (Pub. L. 115–271, October 24, 2018) outlines national strategies to help address America's opioid and substance use disorders (SUD) crisis, and advances policies to improve the treatment of pain and SUD. The SUPPORT Act recognizes the importance of opioid-related medication management, as well as the overall need to identify SUD in the Medicare

[11] *https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.*

[12] *https://www.samhsa.gov/data/report/preliminary-dawn-data-review.*

[13] *https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.*

[14] *https://www.cdc.gov/drugoverdose/pdf/assessing_benefits_harms_of_opioid_therapy-a.pdf.*

[15] *https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.*

[16] *https://nam.edu/event/living-with-chronic-pain-perspectives-from-persons-with-lived-experience/.*

beneficiary population. Sections 2002 and 6086 of the SUPPORT Act are of particular importance regarding pain management. For beneficiaries with chronic pain, section 2002 of the SUPPORT Act amended sections 1861(ww) and (hhh)(2) of the Act to include a review of any current opioid prescriptions in conjunction with the initial preventive physical examination (the ''Welcome to Medicare'' visit) and annual wellness visit (AWV). The opioid prescription review is to include a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's pain severity and current treatment plan, the provision of information on non-opioid treatment options, and referral to a specialist, if appropriate. Section 2002 also amended sections 1861(ww) and (hhh)(2) of the Act to add a screening for potential SUDs to the Welcome to Medicare visit and the AWV, and to add referral to a specialist, as appropriate, to the AWV.

Section 6086 of the SUPPORT Act, the *Dr. Todd Graham Pain Management Study*, will provide HHS and CMS with key information about services delivered to Medicare beneficiaries with acute or chronic pain, help in understanding the current landscape of pain relief options for Medicare beneficiaries, and inform decisions around payment and coverage for pain management interventions, including those that minimize the risk of SUD. CMS has worked with the Agency for Healthcare Research and Quality, which has undertaken three topic briefs and two systematic reviews to inform Medicare coverage for the treatment of acute and chronic pain. CMS has also worked with HHS's Office of the Secretary for Planning and Evaluation to write a Report on the Study, which will be submitted to Congress. CMS will post a completed copy of the Report on our website. The Report will address questions regarding coverage and payment for evidence-based interventions for acute and chronic pain in Medicare, barriers to access, costs and benefits of expanding or revising benefits not currently covered, and legislative and administrative options to improve pain interventions.

We believe it is important to highlight the role of a person-centered approach to pain care. The National Quality Forum, which as its core work defines measures and health care practices as the best, evidence-based approaches to improving care, has defined person-centered planning as ''a facilitated, individual-directed, positive approach to the planning and coordination of a person's services and supports based on individual aspirations, needs, preferences, and values,'' and stated that the ''goal of person-centered planning is to create a plan that would optimize the person's self-defined quality of life, choice, and control, and self-determination through meaningful exploration and discovery of unique preferences and needs and wants in areas including, but not limited to, health and well-being, relationships, safety, communication, residence, technology, community, resources, and assistance.'' [17] These general principles should also apply in the treatment of individuals with pain, where clinicians confirm and affirm the individual's recovery and/or maintenance goals, and focus on those, where treatment is a means to an end.[18] For example, one goal might be to not rely on aiming to reduce a simple pain score, such as a numeric or visual score, but to evaluate function for example, through a tool such as the Defense and Veterans Pain Rating scale,[19] which integrates functional status, and then aim to optimize physical function and mental function in the beneficiary with chronic pain.

We recognize that there are no existing codes that specifically describe the work of the clinician involved in performing the tasks necessary to perform pain management care. We believe there are complexities in treating pain management patients that could include lifestyle discussion, ongoing medication management (such as opioid tapering or discontinuation, when appropriate), behavioral health care, preparation and updating of a care plan, consideration of federal and other opioid prescribing limits and guidelines, Prescription Drug Monitoring Program checks, electronic prescribing requirements, special licensing requirements (controlled substance licenses; buprenorphine ''X-waivers''), interdisciplinary interactions, prescription drug coverage, CMS high-prescriber oversight, consideration of out-of-pocket costs, and other issues. As one example, decreasing or discontinuing opioid treatment requires careful, person-centered consideration of all of these aspects of providing care. These unique challenges often adversely impact the delivery of care, and subsequent access to care, for beneficiaries with chronic pain. Current Medicare payment methodologies such as Chronic Care Management (CCM) support chronic disease management, though may not provide adequate payment to health care providers or systems to holistically care for beneficiaries with chronic pain; we believe the complexity and resources required for safe and effective pain management may not be adequately captured and paid through these codes.

We believe that creating separate or add-on payment for care and management for people with pain might provide opportunities to better leverage services furnished using telecommunications technology and non face-to-face care while expanding access to treatment for pain. Such an additional payment could potentially be effective in preventing or reducing the need for acute services such as fall avoidance, and reduce the need for treatment for mental disorders such as depression, anxiety, and sleep disorders which may occur in some individuals with pain. There is also reason to believe that addressing chronic pain (for example, pain that lasts more than 3 months) early in its course may result in averting the development of ''high-impact'' chronic pain in some individuals, where they experience at least one major activity restriction (for example, unable to work, go to school, perform household chores). These individuals report more severe pain, more difficulty with self-care, and higher health care use than others with chronic pain. From a social determinants of health perspective, Blacks, Native Americans, persons of Asian/Indian descent, older adults, and people with less education, and single individuals report more high impact chronic pain.[20]

In 2019, 12.2 million individuals were enrolled in both Medicaid and Medicare, including people age 65 and older and younger beneficiaries with disabilities. Many have multiple chronic conditions, physical disabilities, behavioral health conditions, and cognitive impairments and on average, use more services and supports than those enrolled in only Medicaid or Medicare, with higher per capita costs. Dually eligible beneficiaries often have multiple social risk factors such as housing insecurity and homelessness, food insecurity, inadequate access to transportation, and low health literacy. A 2019 study [21] on dually eligible beneficiaries using ''high dose'' opioids to treat pain between 2006 through 2015

[17] *https://www.qualityforum.org/Home.aspx.*

[18] *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=89422.*

[19] *https://www.va.gov/painmanagement/resources.asp.*

[20] *https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain.*

[21] *https://www.macpac.gov/wp-content/uploads/2020/06/Chapter-1-Integrating-Care-for-Dually-Eligible-Beneficiaries-Background-and-Context.pdf.*

indicated that the common conditions in beneficiaries studied were chronic pain, migraine, rheumatoid arthritis, osteoporosis, HIV/AIDS, viral hepatitis, and SUD.[22]

We are soliciting comment on whether we should consider creating separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment. These activities could include, but are not limited to the following:

- Diagnosis;
- Assessment and monitoring;
- Administration of a validated rating scale(s);
- Development and maintenance of a person-centered care plan;
- Overall treatment management;
- Facilitation and coordination of any needed behavioral health treatment;
- Medication management;
- Patient education and self-management;
- Crisis care;
- Specialty care coordination such as complementary and integrative pain care, and SUD care; and
- Other aspects of pain and/or behavioral health services, including care rendered through telehealth modalities.

We are interested in feedback regarding whether the resource costs involved in furnishing these activities would be best captured through an add-on code to be billed with an E/M visit or a standalone code. To price such a code, we could consider using a crosswalk to the valuation and inputs for reference codes such as CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment*), HCPCS code G2064 (*Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month*), HCPCS code G0108 (*Diabetes outpatient self-management training services, individual, per 30 minutes*), or other services paid under the PFS with similar resource costs.

We also seek information on which healthcare settings and stages in treatment these transitions from opioid dependence are occurring, as well as what types of practitioners furnish these services. We are soliciting comments on whether the specific activities we identify above are appropriate, and whether there are other activities that should be included. We are interested in stakeholder feedback regarding how we could define and value separate coding or an E/M add-on code. We also seek comment on whether any components of the service could be provided ''incident to'' the services of the billing physician who is managing the beneficiary's overall care similar to the structure of the Behavioral Health Integration (BHI) codes, which can include BHI services that are not delivered personally by the billing practitioner and delivered by other members of the care team (except the beneficiary), under the direction of the billing practitioner on an incident to basis (as an integral part of services delivered by the billing practitioner), subject to applicable state law, licensure, and scope of practice. The other care team members are either employees or working under contract to the practitioner who bills for BHI services.

We welcome feedback from stakeholders and the public on potential separate coding or an E/M add-on code for chronic pain management for our consideration for CY 2022 or for future rulemaking.

BILLING CODE 4120–01–P

[22] *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/Downloads/OpioidsDataBrief_2006-2015_10242018.pdf.*

TABLE 13: CY 2022 Proposed Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
00537	Anesthesia for cardiac electrophysiologic procedures including radiofrequency ablation	7.00	12.00	10.00	No
01XX2	Anesthesia for percutaneous image guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic	NEW	4.00	4.00	No
01XX3	Anesthesia for percutaneous image guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral	NEW	4.00	4.00	No
01XX4	Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic	NEW	4.00	4.00	No
01XX5	Anesthesia for percutaneous image guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral	NEW	4.00	4.00	No
01XX6	Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures (eg. kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic	NEW	6.00	5.00	No
01XX7	Anesthesia for percutaneous image guided neuromodulation or intravertebral procedures (eg. kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral	NEW	6.00	5.00	No
0X12T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	NEW	C	C	No
21315	Closed treatment of nasal bone fracture with manipulation; without stabilization	1.83	2.00	0.96	No
21320	Closed treatment of nasal bone fracture with manipulation; with stabilization	1.88	2.33	1.59	No
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	13.50	15.00	15.00	No
28001	Incision and drainage, bursa, foot	2.78	2.00	2.00	No
28002	Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space	5.34	3.50	2.79	No
28003	Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas	9.06	5.28	5.28	No
338X0	Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta	NEW	14.00	10.81	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
338X1	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches	NEW	21.70	18.27	No
338X2	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches	NEW	17.97	14.54	No
33XX3	Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	NEW	18.50	18.50	No
33XX4	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	NEW	2.50	2.50	No
33XX5	Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)	NEW	14.31	14.31	No
33XXX	Transcatheter placement and subsequent removal of / cerebral embolic protection device(s), including arterial / access, catheterization, imaging, and radiological / supervision and interpretation, percutaneous	NEW	2.50	2.50	No
35600	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, open	NEW	4.00	3.59	No
35XX0	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic	NEW	3.75	3.34	No
38505	Biopsy or excision of lymph node(s); by needle, superficial (eg, cervical, inguinal, axillary)	1.14	1.59	1.59	No
42XXX	Drug induced sleep endoscopy; with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing; flexible, diagnostic	NEW	1.90	1.90	No
434XX	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])	NEW	15.50	13.29	No
46020	Placement of seton	3.00	3.50	1.86	No
46030	Removal of anal seton, other marker	1.26	2.00	1.48	No
53XX1	Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance	NEW	C	C	No
53XX2	Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance	NEW	C	C	No
53XX3	Periurethral transperineal adjustable balloon continence device; removal, each balloon	NEW	C	C	No
53XX4	Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume	NEW	C	C	No
617X1	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion	NEW	20.00	19.06	No
617X2	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	NEW	24.00	22.67	No
630X1	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess	NEW	4.44	2.31	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment				
630XX	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment	NEW	5.55	3.08	No
645X1	Open implantation of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	NEW	16.00	14.00	No
645X2	Revision or replacement of hypoglossal nerve neruostimulator array and distal respiratory sensor electrode or electrode array, including connection to an existing pulse generator	NEW	16.50	14.50	No
645X3	Removal of hypoglossal nerve neruostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array	NEW	14.00	12.00	No
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint	3.84	3.42	3.31	No
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint	1.32	1.32	1.32	No
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint	3.78	3.42	3.32	No
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint	1.16	1.16	1.16	No
646X0	Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; first two vertebral bodies, lumbar or sacral	NEW	8.25	7.15	No
646X1	Thermal destruction of intraosseous basivertebral nerve, inclusive of all imaging guidance; each additional vertebral body, lumbar or sacral	NEW	4.87	3.77	No
66174	Transluminal dilation of aqueous outflow canal; without retention of device or stent	12.85	8.53	7.62	No
66175	Transluminal dilation of aqueous outflow canal; with retention of device or stent	13.60	10.25	9.34	No
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation	10.25	10.25	10.25	No
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation	7.35	7.35	7.35	No
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or	C	13.15	C	Yes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation				
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	C	10.25	C	Yes
669X1	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	NEW	12.13	10.31	No
669X2	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	NEW	9.23	7.41	No
67141	Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage; cryotherapy, diathermy	6.15	2.53	2.53	No
67145	Prophylaxis of retinal detachment (eg, retinal break, lattice degeneration) without drainage; photocoagulation	6.32	2.53	2.53	No
67311	Strabismus surgery, recession or resection procedure; 1 horizontal muscle	7.77	5.93	5.93	No
67312	Strabismus surgery, recession or resection procedure; 2 horizontal muscles	9.66	9.50	9.50	No
67314	Strabismus surgery, recession or resection procedure; 1 vertical muscle (excluding superior oblique)	8.79	5.93	5.93	No
67316	Strabismus surgery, recession or resection procedure; 2 or more vertical muscles (excluding superior oblique)	10.93	10.31	10.31	No
67318	Strabismus surgery, any procedure, superior oblique muscle	9.12	9.80	9.80	No
67320	Transposition procedure (eg, for paretic extraocular muscle), any extraocular muscle (specify)	5.40	3.00	3.00	No
67331	Strabismus surgery on patient with previous eye surgery or injury that did not involve the extraocular muscles	5.13	2.00	2.00	No
67332	Strabismus surgery on patient with scarring of extraocular muscles (eg, prior ocular injury, strabismus or retinal detachment surgery) or restrictive myopathy (eg, dysthyroid ophthalmopathy)	5.56	3.50	3.50	No
67334	Strabismus surgery by posterior fixation suture technique, with or without muscle recession	5.05	2.06	2.06	No
67335	Placement of adjustable suture(s) during strabismus surgery, including postoperative adjustment(s) of suture(s)	2.49	3.23	3.23	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
67340	Strabismus surgery involving exploration and/or repair of detached extraocular muscle(s)	6.00	5.00	5.00	No
68XXX	Insertion of drug-eluting implant, including punctal dilation, when performed, into lacrimal canaliculus, each	NEW	0.49	0.49	No
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor	14.45	8.69	8.69	No
69717	Revision/replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor	15.43	8.80	8.80	No
69X50	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	NEW	9.77	9.77	No
69X51	Revision/replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	NEW	9.77	9.77	No
69X52	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor	NEW	5.93	5.93	No
69X53	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	NEW	7.13	7.13	No
74301	Cholangiography and/or pancreatography; additional set intraoperative, radiological supervision and interpretation	0.21	0.21	0.21	No
77X01	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual x-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture risk	NEW	0.20	0.20	No
77X02	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere	NEW	0.00	0.00	No
77X03	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only	NEW	0.00	0.00	No
77X04	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture risk only, by other qualified healthcare professional	NEW	0.20	0.20	No
80XX0	Pathology clinical consultation; for a clinical problem with limited review of patient's history and medical records and straightforward medical decision making. When using time for code selection, 5-20 minutes of total time is spent on the date of the consultation.	NEW	0.50	0.43	No
80XX1	Pathology clinical consultation; for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making. When using time for code selection, 21-40 minutes of total time is spent on the date of the consultation.	NEW	0.91	0.91	No
80XX2	Pathology clinical consultation; for a highly complex clinical problem, with comprehensive review of patient's history and medical records and high level of medical decision making. When using time for code selection, 41-60 minutes of total time is spent on the date of the consultation.	NEW	1.80	1.71	No
80XX3	Pathology clinical consultation; prolonged service, each additional 30 minutes	NEW	0.80	0.80	No
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report	2.49	2.24	2.24	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report	1.00	1.00	0.90	No
9111X	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report	NEW	2.41	2.41	No
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ecg data storage (retrievable with query) with ecg triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional	0.52	0.52	0.43	No
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional	0.00	0.00	0.00	No
933X0	3D echocardiographic imaging and postprocessing during transesophageal echocardiography or transthoracic echocardiography for congenital cardiac anomalies for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, intratcrial septum, interventricular septum) and function, when performed	NEW	0.50	0.50	No
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium	2.10	1.75	1.50	No
93653	Comprehensive electrophysiologic evaluation including with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	14.75	18.49	14.75	Yes
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording, and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and His bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy	19.75	19.75	19.75	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	including left ventricular pacing and recording, when performed				
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia	7.50	6.50	5.50	No
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography including imaging supervision and interpretation, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, right ventricular pacing/recording, and his bundle recording, when performed	19.77	20.00	19.77	No
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation	7.50	6.50	5.50	No
93X1X	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections	NEW	3.99	3.99	No
93X2X	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections	NEW	6.10	6.10	No
93X3X	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections	NEW	6.00	5.50	No
93X4X	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections	NEW	7.91	6.84	No
93X5X	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal connections	NEW	9.99	8.88	No
93X6X	Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects	NEW	1.75	1.44	No
946X1	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session)	NEW	0.55	0.36	No
946X2	Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)	NEW	0.69	0.56	No
989X1	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment	NEW	0.00	0.00	No
989X2	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg,	NEW	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days				
989X3	Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days	NEW	0.00	0.00	No
989X4	Remote therapeutic monitoring treatment, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes	NEW	0.62	0.62	No
989X5	Remote therapeutic monitoring treatment, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes	NEW	0.61	0.61	No
99439	Chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; • comprehensive care plan established, implemented, revised, or monitored.: each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	0.54	0.70	0.70	No
99487	Complex chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, • comprehensive care plan established, implemented, revised, or monitored, • moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	1.00	1.81	1.81	No
99489	Complex chronic care management services, with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, • comprehensive care plan established, implemented, revised, or monitored, • moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	0.50	1.00	1.00	No
99490	Chronic care management services, with the following required elements:	0.61	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	• multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; • comprehensive care plan established, implemented, revised, or monitored.: first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.				
99491	Chronic care management services with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;, • comprehensive care plan established, implemented, revised, or monitored.; first 30 minutes, provided personally by a physician or other qualified health care professional, per calendar month.	1.45	1.50	1.50	No
99X21	Chronic care management services with the following required elements: • multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;, • chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;, • comprehensive care plan established, implemented, revised, or monitored.; each additional 30 minutes by a physician or other qualified health care professional, per calendar month	NEW	1.00	1.00	No
99X22	Principal care management services, for a single high-risk disease, with the following required elements: • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities • ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month	NEW	1.45	1.45	No
99X23	Principal care management services, for a single high-risk disease, with the following required elements: • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan,	NEW	1.00	1.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	• the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities • ongoing communication and care coordination between relevant practitioners furnishing care; additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month				
99X24	Principal care management services, for a single high-risk disease, with the following required elements; • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, • ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month.	NEW	1.00	1.00	No
99X25	Principal care management services, for a single high-risk disease, with the following required elements; • one complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, • the condition requires development, monitoring, or revision of disease-specific care plan, • the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities, • ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	NEW	0.71	0.71	No
GXXAB	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area	NEW	-	C	No
GXXAC	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof	NEW	-	C	No
GXXAD	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children	NEW	-	C	No
GXXAE	Application of synthetic skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area,	NEW	-	C	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	or part thereof, or each additional 1% of body area of infants and children, or part thereof				
GXXAF	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; first 25 sq cm or less wound surface area	NEW	-	C	No
GXXAG	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm, including provision of synthetic skin substitute; each additional 25 sq cm wound surface area, or part thereof	NEW	-	C	No
GXXAH	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; first 100 sq cm wound surface area, or 1% of body area of infants and children	NEW	-	C	No
GXXAI	Application of synthetic skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm, including provision of synthetic skin substitute; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof	NEW	-	C	No

TABLE 14: CY 2022 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
46020	Placement of seton	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
46020	Placement of seton	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.67
46020	Placement of seton	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
46020	Placement of seton	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-5.90
46020	Placement of seton	L037D	RN/LPN/MTA	F	Coordinate post-procedure services	3	0	G1: See preamble text	-1.77
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services (including test results)	3	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Complete preservice diagnostic and referral forms	5	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.95
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Provide preservice education/obtain consent	7	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.13

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	5	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.18
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Coordinate post-procedure services	3	0	G1: See preamble text	-1.77
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	10	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.13
46030	Removal of rectal marker	L037D	RN/LPN/MTA	F	Complete preservice diagnostic and referral forms	5	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.18
46030	Removal of rectal marker	L037D	RN/LPN/MTA	NF	Complete pre-procedure phone calls and prescription	3	0	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
617X1	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.67
617X1	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
617X1	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services	20	10	L8: Standard preservice clinical labor time for	-5.90

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					(including test results)			procedures with 0/10 day global periods	
617X1	Litt icr 1 traj 1 smpl les	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
617X2	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.77
617X2	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-2.36
617X2	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Provide preservice education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-7.67
617X2	Litt icr mlt trj mlt/cplx ls	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-5.90
68XXX	Insj rx elut implt lac canal	EL006	lane, screening (opht)	NF		9	5	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.55
69714	Impltj oi implt skl perq esp	L037D	RN/LPN/MTA	F	Post-operative visits (total time)	108	99	L9: Refined clinical labor to align with number of post-operative visits	-5.31
69717	Revj/rplcmt oi implt prq esp	L037D	RN/LPN/MTA	F	Post-operative	108	99	L9: Refined clinical labor to align with number of post-operative visits	-5.31

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					visits (total time)				
80XX0	Path clin consltj sf 5-20	EP024	microscope, compound	NF		15	0	G1: See preamble text	-0.47
80XX0	Path clin consltj sf 5-20	L035A	Lab Tech/Histotechnologist	NF	Accession and enter information	4	0	L2: Clinical labor task redundant with clinical labor task PA008	-2.48
80XX1	Path clin consltj mod 21-40	EP024	microscope, compound	NF		30	0	G1: See preamble text	-0.95
80XX1	Path clin consltj mod 21-40	L035A	Lab Tech/Histotechnologist	NF	Accession and enter information	4	0	L2: Clinical labor task redundant with clinical labor task PA008	-2.48
80XX2	Path clin consltj high 41-60	EP024	microscope, compound	NF		54	0	G1: See preamble text	-1.70
80XX2	Path clin consltj high 41-60	L035A	Lab Tech/Histotechnologist	NF	Accession and enter information	4	0	L2: Clinical labor task redundant with clinical labor task PA008	-2.48
80XX3	Path clin consltj prolng svc	EP024	microscope, compound	NF		30	0	G1: See preamble text	-0.95
91111	Esophageal capsule endoscopy	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	9	6	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-1.77
93228	Remote 30 day ecg rev/report	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	10	2	G1: See preamble text	-4.72
93229	Remote 30 day ecg tech supp	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	0	G1: See preamble text	-12.24
946X1	Phy/qhp op pulm rhb w/o mntr	L042B	Respiratory Therapist	NF	Provide education/obtain consent	15	2	L1: Refined time to standard for this clinical labor task	-9.10

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF)/ Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
946X2	Phy/qhp op pulm rhb w/mntr	L042B	Respiratory Therapist	NF	Provide education/obtain consent	15	2	L1: Refined time to standard for this clinical labor task	-9.10

TABLE 15: CY 2022 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
69714	Impltj oi implt skl perq esp	EF008	chair with headrest, exam, reclining	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.12
69714	Impltj oi implt skl perq esp	EQ170	light, fiberoptic headlight w-source	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
69714	Impltj oi implt skl perq esp	EQ183	microscope, operating	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.25
69714	Impltj oi implt skl perq esp	EQ234	suction and pressure cabinet, ENT (SMR)	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
69717	Revj/rplcmt oi implt prq esp	EF008	chair with headrest, exam, reclining	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.12
69717	Revj/rplcmt oi implt prq esp	EQ170	light, fiberoptic headlight w-source	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
69717	Revj/rplcmt oi implt prq esp	EQ183	microscope, operating	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.25
69717	Revj/rplcmt oi implt prq esp	EQ234	suction and pressure cabinet, ENT (SMR)	F		108	99	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
91111	Esophageal capsule endoscopy	EF023	table, exam	NF		44	41	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
91111	Esophageal capsule endoscopy	EQ146	kit, capsule endoscopy recorder	NF		64	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.14
946X1	Phy/qhp op pulm rhb w/o mntr	EQ118	exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board)	NF		93	80	E15: Refined equipment time to conform to changes in clinical labor time	-0.37
946X2	Phy/qhp op pulm rhb w/mntr	EQ118	exercise equipment (treadmill, bike, stepper, UBE, pulleys, balance board)	NF		93	80	E15: Refined equipment time to conform to changes in clinical labor time	-0.37

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
946X2	Phy/qhp op pulm rhb w/mntr	EQ211	pulse oximeter w-printer	NF		93	80	E15: Refined equipment time to conform to changes in clinical labor time	-0.09

TABLE 16: CY 2022 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
88341, 88342, 88344	E-Bar Printer Ribbon (Ventana 1632900) (prints 8100 labels)	SL476	$117.40	$141.67	21%	3	1,772,367
88341, 88342, 88344, 88360, 88361	Reaction buffer 10X (Ventana 950-300)	SL478	$0.030	$0.037	23%	3	2,020,210
88341, 88342, 88344, 88360, 88361	Liquid coverslip (Ventana 650-010)	SL479	$0.030	$0.051	70%	3	2,020,210
88341, 88342, 88344, 88360, 88361	SSC (10X) (Ventana 950-110)	SL480	$0.010	$0.051	405%	3	2,020,210
88341, 88342, 88344, 88360, 88361	EZ Prep (10X) (Ventana 950-102)	SL481	$0.034	$0.034	-1%	3	2,020,210
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	$16.12	$18.01	12%	3	247,843
91110, 91111	kit, capsule endoscopy recorder	EQ146	$21,285.44	$17,701.58	-17%	5	24,027
91110, 91111	video system, capsule endoscopy (software, computer, monitor, printer)	ES029	$9,425.40	$10,181.55	8%	1	24,027

TABLE 17: CY 2022 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
0001A, 0002A, 0011A, 0012A, 0021A, 0022A, 0031A	refrigerator, vaccine medical grade, w-data logger sngl glass door	EF049	7,674.43	2	-
0001A, 0002A	freezer, under counter, ultra cold 3.7 cu ft	EF050	16,516.36	1	-
9111X	PillCam COLON capsule	SD346	625.00	4	0
93229	MCT Electrode Patch Kit	SD345	4.85	1	251,398
933X0	3D Echocardiography Probe	ER121	31,754.30	1	1
989X3	Remote musculoskeletal therapy system	EQ402	1,000.00	1	TBD
No codes	PillCam sensor sleeves	SD347	5.00	5	0

TABLE 18: CY 2022 No PE Refinements

HCPCS	Description
00537	Anesth cardiac electrophys
01XX2	Anes drg/aspir crv/thrc
01XX3	Anes drg/aspir lmbr/sac
01XX4	Anes nulyt agt crv/thrc
01XX5	Anes nulyt agt lmbr/sac
01XX6	Anes neuromd/ntrvrt crv/thrc
01XX7	Anes neuromd/ntrvrt lmbr/sac
21315	Clsd tx nsl fx mnpj wo stblj
21320	Clsd tx nsl fx w/mnpj&stablj
22867	Insj stablj dev w/dcmprn
28001	Drainage of bursa of foot
28002	Treatment of foot infection
28003	Treatment of foot infection
33XX3	Open excl laa any method
33XX5	Thrscp excl laa any method
38505	Needle biopsy lymph nodes
42XXX	Dise eval slp do brth flx dx
434XX	Transorl lwr esophgl myotomy
645X1	Opn mpltj hpglsl nstm ary pg
645X2	Rev/rplct hpglsl nstm ary pg
645X3	Rmvl hypglsl nstim ary pg
64633	Destroy cerv/thor facet jnt
64634	Destroy c/th facet jnt addl
64635	Destroy lumb/sac facet jnt
64636	Destroy l/s facet jnt addl
646X0	Trml dstrj ios bvn 1st 2 l/s
66174	Translum dil eye canal
66175	Trnslum dil eye canal w/stnt
66982	Xcapsl ctrc rmvl cplx wo ecp
66984	Xcapsl ctrc rmvl w/o ecp
66987	Xcapsl ctrc rmvl cplx w/ecp
66988	Xcapsl ctrc rmvl w/ecp
669X1	Xcpsl ctrc rmvl cplx insj 1+
669X2	Xcapsl ctrc rmvl insj 1+
67141	Proph rta dtchmnt crtx dthrm
67145	Proph rta dtchmnt pc
67311	Revise eye muscle
67312	Revise two eye muscles
67314	Revise eye muscle
67316	Revise two eye muscles
67318	Revise eye muscle(s)
69X50	Impltj oi implt skl tc esp
69X51	Revj/rplcmt oi implt tc esp
69X52	Rmvl oi implt skl perq esp
69X53	Rmvl oi implt skl tc esp
77X01	Tbs dxa cal w/i&r fx risk
77X02	Tbs techl prep&transmis data
77X03	Tbs techl calculation only
77X04	Tbs i&r fx rsk qhp
91110	Gi tract capsule endoscopy
9111X	Gi trc img intral colon
933X0	3d echo img cgen hrt anomal
989X1	Rem ther mntr 1st setup&edu
989X2	Rem ther mntr dev sply resp
989X3	Rem ther mntr dv sply mscskl
989X4	Rem ther mntr 1st 20 min
989X5	Rem ther mntr ea addl 20 min
99439	Chrnc care mgmt staf ea addl
99487	Cplx chrnc care 1st 60 min
99489	Cplx chrnc care ea addl 30
99490	Chrnc care mgmt staff 1st 20
99491	Chrnc care mgmt phys 1st 30
99X21	Chrnc care mgmt phys ea addl
99X22	Prin care mgmt phys 1st 30
99X23	Prin care mgmt phys ea addl
99X24	Prin care mgmt staff 1st 30
99X25	Prin care mgmt staff ea addl

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F. Evaluation and Management (E/M) Visits

Over the past several years, CMS has engaged with the AMA and other stakeholders in a process to update coding and payment for office/outpatient evaluation and management (E/M) visits, with recent changes taking effect January 1, 2021 (see 85 FR 84548 through 84574). In light of these changes, we are engaged in an ongoing review of other E/M visit code sets and are proposing a number of refinements to our current policies. The following section will discuss proposed policies regarding split (or shared) visits, critical care services, and teaching physician visits.

1. Split (or Shared) Visits

a. Background

A split (or shared) visit refers to an E/M visit that is performed (''split'' or ''shared'') by both a physician and a NPP who are in the same group. Because the Medicare statute provides a higher PFS payment rate for services furnished by physicians than services furnished by NPPs, we need to address whether and when the physician can bill for split (or shared) visits. For visits in the non-facility (for example, office) setting for which the physician and NPP each perform portions of the visit, the physician can bill for the visit rather than the NPP as long as the visit meets the conditions of payment in our regulations at § 410.26(b)(1) for services furnished ''incident to'' a physician's professional services. However, for visits furnished under similar circumstances in facility settings (for example, in a hospital), our current regulations provide for payment only to the physician or NPP who personally performs all elements of the service, and no payment is made for services furnished ''incident to'' the billing professional's services.

As stated in our regulation at § 410.26(b)(1), Medicare Part B pays for services and supplies furnished ''incident to'' a physician's (or other practitioner's) professional services if those services and supplies are furnished in a noninstitutional setting to noninstitutional patients. In certain institutional (or ''facility'') settings, our longstanding split (or shared) billing

policy allows a physician to bill for an E/M visit when both the billing physician and an NPP in their group each perform portions of the visit, but only if the physician performs a substantive portion of the visit. When the physician bills for such a split (or shared) visit, in accordance with section 1833(a)(1)(N) of the Act, the Medicare Part B payment is equal to 80 percent of the payment basis under the PFS which, under section 1848(a)(1) of the Act, is the lesser of the actual charge or the fee schedule amount for the service. In contrast, if the physician does not perform a substantive portion of such a split (or shared) visit and the NPP bills for it, in accordance with section 1833(a)(1)(O) of the Act, the Medicare Part B payment is equal to 80 percent of the lesser of the actual charge or 85 percent of the fee schedule rate.

Previously, our policy for billing these split (or shared) visits was reflected in several provisions of our Medicare Claims Policy Manual (sections 30.6.1(B), 30.6.12, and 30.6.13(H)) which were withdrawn effective May 9, 2021, in response to a petition under the Department's Good Guidance regulations at 45 CFR 1.5 (see Transmittal 10742 available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10742cp*). In the absence of these manual provisions, the Medicare statute and various broadly applicable regulations continue to apply. In addition to withdrawing the manual provisions, we issued our response to the petition and an accompanying enforcement instruction on May 26, 2021, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Evaluation-and-Management-Visits*). In those documents, we indicated that we intend to address split (or shared) visits and critical care services (addressed below) through rulemaking; and that until we do, we will limit review to the applicable statutory and regulatory requirements for purposes of assessing payment compliance.

The list of applicable statutory and regulatory requirements includes the CY 2021 PFS final rule (85 FR 84549), where CMS generally adopted new CPT prefatory language and code descriptors for office/outpatient E/M visits. The new CPT guidelines for E/M services introduced a CPT definition of a split (or shared) visit for the first time, effective January 1, 2021. This new CPT definition was part of CPT's new guidelines indicating how to select the visit level based on time, which can be done for all office/outpatient E/M visits starting in 2021. The CPT guidelines that we are referring to are published in the CPT Codebook, in a section titled ''Evaluation and Management Services (E/M) Guidelines.'' [23] In this section of our proposed rule, we use the term ''CPT E/M Guidelines'' to refer to this material.

In the CY 2021 PFS final rule (85 FR 84549), we stated that we are generally adopting the CPT E/M Guidelines for the new office/outpatient E/M visit codes. However, the CPT E/M Guidelines do not address many issues that arise in the context of PFS payment for split (or shared) visits, such as which practitioner should report the visit when elements of the visit are performed by different practitioners; whether a substantive portion of the visit must be performed by the billing practitioner; whether practitioners must be in the same group to bill for a split (or shared) visit; or the settings of care where split (or shared) visits may be furnished and billed. The CPT E/M Guidelines simply state, ''A split or shared visit is defined as a visit in which a physician and other qualified health care professional(s) jointly provide the face-to-face and non-face-to-face work related to the visit. When time is being used to select the appropriate level of services for which time-based reporting of shared or split visits is allowed, the time personally spent by the physicians and other qualified health care professional(s) assessing and managing the patient on the date of the encounter is summed to define total time. Only distinct time should be summed for split or shared visits (that is, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).'' [24]

In contrast, to ensure appropriate PFS payment, our policy for split (or shared) visits, as expressed in the recently withdrawn manual provisions, is that the physician may bill for a split (or shared) visit only if they perform a substantive portion of the visit, and the practitioners must be in the same group and furnishing the visit in specified settings in order to bill for a split (or shared) visit. Our manual also limited billing for split (or shared) visits to services furnished to established patients. In this proposed rule, we are making a number of proposals to address the recently withdrawn manual sections and improve transparency and clarity regarding our policies on billing for split (or shared) visits, to update them to account for recent revisions to E/M visit coding and payment, and to revise our regulations to reflect these policies.

b. Definition of Split (or Shared) Visits

We are proposing to define a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group, in accordance with applicable laws and regulations. We propose to add this definition to a new section of our regulations at § 415.140.

Additionally, we propose to define split (or shared) visits as those that:

- Are furnished in a facility setting by a physician and an NPP in the same group, where the facility setting is defined as an institutional setting in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under our regulation at § 410.26(b)(1).
- Are furnished in accordance with applicable law and regulations, including conditions of coverage and payment, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit).

We are proposing to revise our regulations at § 415.140 to codify this definition.

We believe that limiting the definition of split (or shared) visits to include only E/M visits in institutional settings, for which ''incident to'' payment is not available, will allow for improved clarity, and clearly distinguish, the policies applicable to split (or shared) visits, from the policies applicable to services furnished incident to the professional services of a physician. We do not see a need for split (or shared) visit billing in the office setting, because the ''incident to'' regulations govern situations where an NPP works with a physician who bills for the visit, rather than billing under the NPP's own provider number.

We are also proposing to modify our policy to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain Skilled Nursing Facility/Nursing Facility (SNF/NF) E/M visits. We are proposing these modifications to the current policy and conditions of payment for split (or shared) visits, discussed below, to account for changes that have occurred in medical practice patterns, including

[23] 2021 CPT Codebook, p. 5.

[24] 2021 CPT Codebook, p. 7.

the evolving role of NPPs as part of the medical team.

c. Definition of Substantive Portion

(1) More Than Half of the Total Time

As stated earlier, only the physician or NPP who performs the substantive portion of the split (or shared) visit would bill for the visit. We are proposing to define ''substantive portion'' as more than half of the total time spent by the physician and non-physician practitioner performing the visit. We note that our withdrawn manual instructions contained a few definitions of ''substantive portion.'' For example, one section defined substantive portion as any face-to-face portion of the visit, while another section defined it as one of the three key components of an E/M visit—either the history of present illness (HPI), physical exam, and/or medical decision-making (MDM). Given recent changes in the CPT E/M Guidelines, HPI and physical exam are no longer necessarily included in all E/M visits, because as noted above, for office/outpatient E/M visits, the visit level can now be selected based on either MDM or time, and history and exam are performed only as medically appropriate. Accordingly, defining ''substantive portion'' as one of these three key components is no longer a viable approach. Similarly, MDM is not easily attributed to a single physician or NPP when the work is shared, because MDM is not necessarily quantifiable and can depend on patient characteristics (for example, risk). We believe that time is a more precise factor than MDM to use as a basis for deciding which practitioner performs the substantive portion of the visit.

We also do not believe it would be appropriate to consider the performance of any portion of the visit—with or without direct patient contact—as a substantive portion. For instance, we do not believe it would be appropriate to consider a brief or minor interaction, with or without direct patient contact, such as where the physician merely ''pokes their head'' into the room, to be a substantive portion of the visit. Therefore, we are proposing to define ''substantive portion'' as more than half of the total time spent by the physician and NPP performing the split (or shared) visit. We are proposing to revise our regulation at § 415.140 to codify this definition.

We recognize that the billing practitioner, who would be the practitioner providing the substantive portion of the visit, could select the level for the split (or shared) visit based on MDM, but we nonetheless propose to base the definition of substantive portion on the amount of time spent by the physician and NPP providing the visit. We recognize that this policy would necessitate the practitioners' tracking and documenting the time they spent for these visits. However, we believe that practitioners are likely to increasingly time their visits for purposes of visit level selection independent of our split (or shared) visit policies, given recent changes to the CPT E/M Guidelines, and the fact that critical care visits are already timed. Accordingly, we do not believe this would comprise a substantial new burden.

(2) Distinct Time

We propose that the distinct time of service spent by each physician or NPP furnishing a split (or shared) visit would be summed to determine total time and who provided the substantive portion (and therefore bills for the visit). This would be consistent with the CPT E/M Guidelines stating that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).[25] For example, if the NPP first spent 10 minutes with the patient and the physician then spent another 15 minutes, their individual time spent would be summed to equal a total of 25 minutes. The physician would bill for this visit since they spent more than half of the total time (15 of 25 total minutes). If, in the same situation, the physician and NPP met together for five additional minutes (beyond the 25 minutes) to discuss the patient's treatment plan, that overlapping time could only be counted once for purposes of establishing total time and who provided the substantive portion of the visit. The total time would be 30 minutes, and the physician would bill for the visit since they spent more than half of the total time (20 of 30 total minutes).

(3) Qualifying Time

Drawing on the CPT E/M Guidelines, we are proposing a listing of activities that could count toward total time for purposes of determining the substantive portion. For visits that are not critical care services, we are proposing the same listing of activities that can count when time is used to select E/M visit level, specifically the following activities, when performed and regardless of whether or not they involve direct patient contact:

- Preparing to see the patient (for example, review of tests).
- Obtaining and/or reviewing separately obtained history.
- Performing a medically appropriate examination and/or evaluation.
- Counseling and educating the patient/family/caregiver.
- Ordering medications, tests, or procedures.
- Referring and communicating with other health care professionals (when not separately reported).
- Documenting clinical information in the electronic or other health record.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver.
- Care coordination (not separately reported).

Practitioners would not count time spent on the following:

- The performance of other services that are reported separately.
- Travel.
- Teaching that is general and not limited to discussion that is required for the management of a specific patient.[26]

Since critical care services can include additional activities that are bundled into the critical care visit code(s), we are proposing a different listing of qualifying activities, discussed in our section below on split (or shared) critical care services. Additionally, we are seeking public comment on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split (or shared) emergency department visits, since those visits also have a unique construct.

(4) Application to Prolonged Services

For office/outpatient E/M visits, as discussed in our CY 2021 PFS final rule (85 FR 84572), HCPCS code G2212 can be used to report prolonged services in 15-minute increments of time beyond the maximum time for a level 5 office/outpatient E/M visit. For all other E/M visits (except critical care and emergency department visits), CPT codes 99354–9 can be used to report prolonged time with or without direct patient contact, when required time increments above the typical time is spent (see CY 2017 PFS final rule, 81 FR 80228–80230 and the Medicare Claims Processing Manual (Pub. 100–02), chapter 12, section 30.6.15 available on our website at *https://www.cms.gov/*

[25] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.7.

[26] 2021 CPT Codebook, p. 8, as clarified in the CPT 2021 Errata and Technical Corrections dated June 7, 2021 and available on the AMA website at *https://www.ama-assn.org/system/files/2021-06/cpt-corrections-errata-2021.pdf.*

Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf).

Our withdrawn manual provisions instructed that practitioners cannot bill prolonged services as a split (or shared) visit. Having reviewed this policy, we believe that codes that are billed as add-on codes for prolonged service time for an E/M visit, which could be furnished and billed as a split (or shared) visit under our proposed policy, should be considered to be part of that E/M visit. Therefore, we are proposing to change our policy to allow a practitioner to bill for a prolonged E/M visit as a split (or shared) visit. Specifically, the physician or practitioner who spent more than half the total time (that is, performed the substantive portion described above) would bill for the primary E/M visit and the prolonged service code(s) when the service is furnished as a split (or shared) visit, if all other requirements to bill for the services were met. The physician and NPP would sum their time together, and whomever furnished more than half of the total time, including prolonged time, (that is, the substantive portion) would report both the primary service code and the prolonged services add-on code(s), assuming the time threshold for reporting prolonged services is met. We note that for critical care visits, the practitioner would not bill prolonged E/M services because the practitioners would instead aggregate their time, as proposed below, to report additional units of critical care services.

d. New and Established Patients, and Initial and Subsequent Visits

Our withdrawn manual provisions stated that when an E/M service is furnished as a split or shared encounter, between a physician and an NPP (that is, an NP, PA, CNS or CNM), the service is considered to have been performed ''incident to'' if the requirements for ''incident to'' are met and the patient is an established patient. This provision was generally interpreted to mean that split (or shared) visits cannot be billed for new patients. The withdrawn manual provisions also did not specify whether the practitioner who bills for the split or shared visit could bill for initial, versus subsequent, split (or shared) visits in the facility setting. After conducting an internal review, including consulting our medical officers, we believe that the practice of medicine has evolved toward a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by practitioners in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued the manual instructions may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of electronic health records (EHRs) and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. After considering and reevaluating our policy, we see no reason to preclude the physician or NPP from billing for split (or shared) visits for a new patient, in addition to an established patient, or for initial and subsequent split (or shared) visits. Therefore, we are proposing to permit the physician or NPP to bill for split (or shared) visits for both new and established patients, as well as for initial and subsequent visits. We believe this approach is also consistent with the CPT E/M Guidelines for split (or shared) visits, which does not exclude these types of visits from being billed when furnished as split (or shared) services.

e. Settings of Care

The concept of split (or shared) visits was developed as an analog in the facility setting to payment policies for services and supplies furnished incident to a physician's or an NPP's professional services in the non-institutional setting. Section 410.26(a)(6) of our regulations defines the non-institutional setting as all settings other than a hospital or SNF. We are proposing to allow billing of split (or shared) visits, including critical care visits, when they are performed in any institutional setting and are proposing to codify the definition of facility setting in the regulation at § 415.140. We discuss our proposals regarding billing for critical care split (or shared) E/M services below (see section II.F. of this proposed rule).

Our withdrawn manual provisions did not allow practitioners to bill for split (or shared) visits that are critical care services or SNF/NF visits. The manual stated that the split (or shared) E/M policy did not apply to critical care services or procedures, and that a split (or shared) E/M service performed by a physician and a qualified NPP of the same group (or employed by the same employer) cannot be reported as a critical care service. It also stated that a split (or shared) E/M visit cannot be reported in the SNF/NF setting. We propose to define split (or shared) visits to be limited to services furnished in institutional settings, as discussed above. As discussed below, we do not see any reason to preclude billing for split (or shared) visits for critical care services, although we are seeking public comment on this issue in particular. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. Where a physician and NPP in the same group take a team approach to furnishing care, as would be the case for split (or shared) visits, even for new patients, initial visits, critical care visits, or SNF/NF visits, we are less concerned about potential disruptions in continuity of care than we might once have been. Rather, we believe that when a visit is shared between a physician and an NPP in the same group, there would be close coordination and an element of collaboration in providing care to the beneficiary.

We do not see any reason to preclude billing for split (or shared) visits for the subset of SNF/NF visits that are not required by our regulations to be performed in their entirety by a physician. Under our current policy, no E/M services can be furnished and billed as split (or shared) visits in the SNF setting. We refer readers to our Conditions of Participation in 42 CFR 483.30 for information regarding the SNF/NF visits that are required to be performed in their entirety by a physician. That regulation requires that certain SNF/NF visits must be furnished directly and solely by a physician. If finalized, our proposal would not apply to the SNF/NF visits that are required to be performed in their entirety by a physician; any SNF/NF visit that is required to be performed in its entirety by a physician cannot and would not be able to be billed as a split (or shared) visit. However, for other visits to which the regulation at § 483.30 does not apply, there is no requirement for a physician to directly and solely perform the visit. We propose that those visits could be furnished and billed as split (or shared) visits.

f. Same Group

In accordance with the current policy outlined in the withdrawn manual provisions, we are proposing that a physician and NPP must be in the same group in order for the physician and NPP to bill for a split (or shared) visit. We believe that in circumstances when a split or (shared) visit is appropriately billed, a physician and NPP are working jointly to furnish all of the work related to the visit with the patient. However, if a physician and NPP are in different groups, we would expect the physician

and NPP to bill independently, and only for the services they specifically and fully furnish. Further, consistent with our withdrawn manual guidance, we note that Medicare does not pay for partial physician's visits, so CPT modifier −52 (reduced services) could not be used to report split (or shared) visits. Thus, if a physician and an NPP who are in different groups each furnish part of an E/M service, but not all of it, then we would not consider either service to be a billable service. Similarly, if two physicians, each in their own private practice, both saw the same patient in the hospital, but neither one fully furnished a billable service—there would be no basis on which to combine their efforts or minutes of service into one billable E/M visit.

We are seeking public comment on whether we should further define ''group'' for purposes of split (or shared) visit billing. While we are not proposing a definition in this proposed rule, we have considered several options, such as requiring that the physician and NPP must be in the same clinical specialty, in which case we would use the approach outlined in the CPT E/M Guidelines; that is the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working.[27] We are also considering an approach under which we would align the definition of ''group'' with the definition of ''physician organization'' at § 411.351. The term ''physician organization'' is defined at § 411.351 for purposes of section 1877 of the Act and our regulations in 42 CFR part 411, subpart J (collectively, the physician self-referral law), and explained further in frequently asked questions available on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.* Another approach would be to consider practitioners with the same billing tax identification number as being in the same group. We are concerned that this particular approach may be too broad in multi-specialty groups or health care systems that include many practitioners who do not typically work together to furnish care to patients in the facility setting. We note that some of these approaches may not align with the definition of ''group'' used for purposes of Medicare enrollment.

[27] 2021 CPT Codebook, p. 6, ''When advanced practice nurses and physician assistants are working with physicians, they are considered as working in the exact same specialty and exact same subspecialties as the physician.''

g. Medical Record Documentation

To ensure program integrity and quality of care, we are proposing that documentation in the medical record must identify the two individual practitioners who performed the visit. The individual who performed the substantive portion (and therefore bills the visit) would be required to sign and date the medical record. We are proposing to revise our regulation at § 415.140 to reflect the conditions of payment for split (or shared) visits as discussed in this section.

h. Claim Identification

We are proposing to create a modifier to describe split (or shared) visits, and we are proposing to require that the modifier must be appended to claims for split (or shared) visits, whether the physician or NPP bills for the visit. Currently, we cannot identify through claims that a visit was performed as a split (or shared) visit, which means that we could know that a visit was performed as a split (or shared) visit only through medical record review. We believe it is important for program integrity and quality considerations to have a way to identify who is providing which E/M services, and how often we are paying at the physician rate for services provided in part by NPPs. (Please see the documentation section below for additional information). The proposed modifier, if finalized, would give CMS insight, directly through our claims data instead of only through medical record review, into the specific circumstances under which these split (or shared) visits are furnished. Such information would be helpful to CMS for program integrity purposes, and could be instructive in considering whether we may need to offer additional clarification to the public, or further revise the policy for these E/M visits in future rulemaking.

We are proposing to revise our regulation at § 415.140 to reflect the conditions of payment for split (or shared) visits as discussed in this section.

Consistent with our current policy, Medicare does not pay for partial E/M visits for which all elements of the service are not furnished. Therefore, we are proposing that the modifier identified by CPT for purposes of reporting partial services (modifier −52 (reduced services)) could not be used to report partial E/M visits, including any partial services furnished as split (or shared) visits. We are also considering whether it is necessary to amend our regulations to explicitly state that Medicare does not pay for partial E/M visits and are interested in public comments on this issue.

2. Critical Care Services (CPT Codes 99291–99292)

As stated previously, in light of updates that we previously finalized for coding and payment for office/outpatient E/M visits, we are proposing a number of refinements to other E/M code sets. Historically, our policy for billing critical care services was reflected in several provisions of the Medicare Claims Processing Manual (sections 30.6.1(B), 30.6.12, and 30.6.13(H)) which were withdrawn effective May 9, 2021, in response to a petition under the Department's Good Guidance regulation at 45 CFR 1.5 (see Transmittal 10742 available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10742cp*). In the absence of these manual provisions, the Medicare statute and various broadly applicable regulations continue to apply. In addition to withdrawing the manual provisions, we issued our response to the petition and accompanying enforcement instruction issued on May 26, 2021, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Evaluation-and-Management-Visits.* In those documents, we indicated that we intend to address split (or shared) visits (addressed above) and critical care services (addressed below) through rulemaking; and that until we do, we will limit review to the applicable statutory and regulatory requirements for purposes of assessing payment compliance. The list of applicable statutory and regulatory requirements includes the CY 2021 PFS final rule (85 FR 84549), where CMS generally adopted new CPT prefatory language and code descriptors for office/outpatient E/M visits. Therefore, in this section of the proposed rule, we are proposing to update our critical care E/M visit policies to improve transparency and clarity, and to account for recent revisions to E/M visit coding and payment.

The CPT 2021® Professional Codebook (hereafter, CPT Codebook) provides guidelines for critical care services in the CPT E/M Guidelines on pp. 5–9 and in prefatory language, code descriptors, and parentheticals on pp. 31–33. We are proposing to adopt the CPT prefatory language for critical care services as currently described in the CPT Codebook, except as otherwise specified in this section of the proposed rule. Should CPT make changes to the guidance for critical care services in a

subsequent edition of the CPT Codebook, we could revisit these policies in future rulemaking.

We are also proposing to clarify our definition of critical care visits, and the requirements governing how critical care visits are reported when more than one practitioner or specialty is involved in furnishing critical care services to a patient. Further, we are proposing to prohibit a practitioner that reports critical care services furnished to a patient from also reporting any other E/M visit for that same patient on the same calendar day that the critical care services are furnished to that patient, and vice versa. Additionally, we are proposing to prohibit practitioners from reporting critical care visits during the same time-period as a procedure with a global surgical period.

a. Definition of Critical Care

Critical care visits are described by CPT codes 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes*) and 99292 (*each additional 30 minutes (List separately in addition to code for primary service*). As stated above, the CPT Codebook defines critical care services in prefatory language on pp. 31–33.

Critical care services were defined in the withdrawn provisions of the Medicare Claims Processing Manual, and that definition tracked closely with the CPT prefatory language regarding critical care services. To improve transparency and clarity, we are proposing to adopt the CPT prefatory language as the definition of critical care services. The CPT prefatory language states that critical care is the direct delivery by a physician(s) or other qualified healthcare professional (QHP) of medical care for a critically ill/injured patient in which there is acute impairment of one or more vital organ systems, such that there is a probability of imminent or life-threatening deterioration of the patient's condition.[28] It involves high complexity decision-making to treat single or multiple vital organ system failure and/or to prevent further life-threatening deterioration of the patient's condition. We continue to believe that the CPT Codebook appropriately delineates coding and definitions for critical care services in order to distinguish them as more intense services that are valued relatively higher than other E/M services. Thus, we are proposing to adopt the CPT prefatory language as the definition of critical care services, and refer readers to the CPT Codebook for additional details.

Under current Medicare policy, a QHP is an individual who is qualified by education, training, licensure/regulation (when applicable), facility privileging (when applicable), and the applicable Medicare benefit category to perform a professional service within their scope of practice and independently report that service (see, for example, 80 FR 70957; 85 FR 84543, 84593). Because the CPT Codebook provides that critical care services can be delivered by a physician or QHP, we are proposing that critical care services may be reported by a physician or NPP who is a QHP as explained above.

The CPT prefatory language specifies that critical care may be furnished on multiple days, and is typically furnished in a critical care area, which can include an intensive care unit or emergency care facility. CPT prefatory language also states that critical care requires the full attention of the physician or NPP, and therefore, for any given time-period spent providing critical care services, the practitioner cannot provide services to any other patient during the same period of time. We are proposing to adopt this CPT prefatory language to improve transparency and clarity of our policy for this service for Medicare billing purposes.

CPT prefatory language and billing and coding guidance bundles several services into critical care visits furnished by a given practitioner when performed during the critical period by the practitioners providing critical care. We are proposing to adopt CPT's listing of bundled services that are part of critical care visits to improve transparency and clarity of our policy for this service. Therefore, we are proposing that the following services would be bundled into critical care visits: Interpretation of cardiac output measurements (93561, 93562), chest X rays (71045, 71046), pulse oximetry (94760, 94761, 94762), blood gases, and collection and interpretation of physiologic data (for example, ECGs, blood pressures, hematologic data); gastric intubation (43752, 43753); temporary transcutaneous pacing (92953); ventilator management (94002–94004, 94660, 94662); and vascular access procedures. As a result, these codes would not be separately billable by a practitioner during the time-period when the practitioner is providing critical care for a given patient. We are also proposing to adopt the CPT prefatory language stating that time spent performing separately reportable procedures or services should be reported separately and should not be included in the time reported as critical care time.

b. Critical Care by a Single Physician or NPP

Our withdrawn manual provisions and the prefatory language in the CPT Codebook cited above both describe the time duration for the correct reporting of critical care services by a single physician or NPP. To improve transparency and clarity of our policy for this service, we are proposing to adopt the CPT prefatory language. Under our proposal, the physician or NPP would report CPT code 99291 for the first 30–74 minutes of critical care services provided to a patient on a given date. Thereafter, they would report CPT code 99292 for additional 30-minute time increments provided to the same patient. We refer readers to the CPT Codebook for examples of the total duration of critical care visits.[29] The prefatory language states that CPT codes 99291 and 99292 are used to report the total duration of time spent by the physician or QHP providing critical care services to a critically ill or critically injured patient, even if the time spent by the practitioner on that date is not continuous; and that non-continuous time for medically necessary critical care services may be aggregated. The CPT Codebook indicates that CPT code 99291 is used to report the first 30–74 minutes of critical care on a given date, and that the code should be used only once per date even if the time spent by the practitioner is not continuous on that date. We are proposing to adopt this rule for critical care services furnished by a single physician or NPP. We note that the prefatory language does not indicate how practitioners should report critical care when a service lasts beyond midnight. We are seeking comment about how practitioners should report CPT codes 99291 and 99292 when a service extends beyond midnight to the following calendar day.

c. Critical Care Services Furnished Concurrently by Different Specialties

The CPT Codebook does not provide any special instructions regarding how to report critical care furnished by more than one physician or practitioner, whether in a split (or shared) visit context or other contexts that might be relevant given the unique nature of critical care and the long timeframes over which patients may receive these services. The CPT E/M Guidelines state broadly that concurrent care is the provision of similar services (for

[28] 2021 CPT Codebook, p. 31.

[29] CPT Codebook, p. 32.

example, hospital visits) to the same patient by more than one physician or other QHP on the same day. The CPT E/M Guidelines state that when concurrent care is provided, no special reporting is required.[30] The CPT E/M Guidelines also state broadly that when time is being used to select the appropriate level of services for which time-based reporting of split (or shared) visits is allowed, the time personally spent by the physician and other QHP(s) assessing and managing the patient on the date of the encounter is summed to define total time; and that only distinct time should be summed for split (or shared) visits (that is, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).[31]

In the context of critical care services, our withdrawn manual provisions provided guidance on concurrent care, and stated that there are situations where physicians or NPPs within a group provide coverage or follow-on care for one another on a single day. The manual also stated that critically ill or injured patients may require the care of more than one practitioner from more than one specialty (regardless of group affiliation), and this work could transpire simultaneously or overlap. Consistent with our current policy, and to improve transparency and clarity of our policy for critical care services, we are proposing that concurrent care occurs where more than one physician or qualified NPP furnishes services to the same patient on the same day. In general, concurrent care is covered when the services of each practitioner are medically necessary, and not duplicative. For example, concurrent care may be medically necessary because of the existence of more than one medical condition requiring diverse specialized medical services, that is, more than one specialty (which can include a qualified NPP as a specialty). In the context of critical care services, a critically ill patient may have more than one medical condition requiring diverse specialized medical services and thus requiring more than one practitioner having different specialties to play an active role in the patient's treatment. Thus, we are proposing that critical care services may be furnished as concurrent care (or concurrently) to the same patient on the same day by more than one practitioner in more than one specialty (for example, an internist and a surgeon, allergist and a cardiologist, neurosurgeon and NPP), regardless of group affiliation, if the service meets the definition of critical care and is not duplicative of other services. However, as for most Medicare-covered services, these critical care services would need to be medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. We are seeking comment on this proposal to better understand current clinical practice for critical care, and when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care services.

d. Critical Care Furnished Concurrently by Practitioners in the Same Specialty and Same Group (Follow-Up Care)

Physician(s) or NPP(s) in the same specialty and in the same group may provide concurrent follow-up care, such as a critical care visit subsequent to another practitioner's critical care visit. This may be as part of continuous staff coverage or follow-up care to critical care services furnished earlier in the day on the same calendar date. According to CPT coding and billing conventions that we generally acknowledge, a practitioner who furnishes a timed service such as critical care would typically need to report the primary service or procedure code before reporting an add-on code. However, we are proposing that when critical care is furnished concurrently by two or more practitioners in the same specialty and in the same group to the same patient on the same day, the individual physician(s) or NPP(s) providing the follow-up or subsequent care would report their time using the code for subsequent time intervals (CPT code 99292), and would not report the primary service code (CPT code 99291). CPT code 99291 would not be reported more than once for the same patient on the same day by these practitioners. This proposal recognizes that multiple practitioners in the same specialty and the same group can maintain continuity of care by providing follow-up care for the same patient on the same day, and is consistent with our current policy as described in the withdrawn manual provisions. Because practitioners in the same specialty and same group cover for one another to provide concurrent critical care services, we believe the total time for critical care services furnished to a patient on the same day by the practitioners in the same group with the same specialty should be reflected as if it were a single set of critical care services furnished to the patient. The practitioner furnishing the initial critical care service would report CPT code 99291, and the practitioner(s) reporting subsequent critical care service time would report CPT code 99292.

Under our current policy, the initial critical care service must be performed by a single physician or qualified NPP. In considering and reevaluating this policy, we believe it would better reflect current medical practice to allow critical care service time spent by more than one practitioner in the same group with the same specialty to be added together for the purposes of meeting the time requirement to bill for the initial critical care service using CPT code 99291. We are proposing this policy for two main reasons. First, we believe this proposal would appropriately recognize that multiple practitioners in the same specialty and group can concurrently furnish critical care services to a patient on a single day. Second, this proposal would conform our policy for the initial critical care service with our proposal described above for multiple practitioners in the same specialty and same group to report CPT code 99292 for their cumulative critical care service time. Thus, we are proposing that where one practitioner begins furnishing the initial critical care service but does not meet the time required to report CPT code 99291, and another practitioner in the same specialty and group continues to deliver critical care to the same patient on the same day, the time spent by those practitioners could be aggregated to meet the time requirement to bill CPT code 99291. Under our proposal, once the cumulative required critical care service time is met to report CPT code 99291, CPT code 99292 would not be reported by the practitioner or another practitioner in the same specialty and group unless and until an additional 30 minutes of critical care services are furnished to the same patient on the same day (114 total minutes). Finally, consistent with our current policy, we are proposing that the aggregated time spent on critical care visits must be medically necessary and each visit must meet the definition of critical care in order to add the times for purposes of meeting the time requirement to bill CPT code 99291. We are seeking comment on this proposal to better understand current clinical practice for critical care, and when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide

[30] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.8.

[31] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.7.

critical care services to a patient on a single day.

e. Split (or Shared) Critical Care Services

Under current CMS policy, critical care services cannot be billed as split (or shared) E/M services. As previously discussed in section II.F.1. of this proposed rule for split (or shared) visits, we believe the practice of medicine has evolved toward a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by clinicians in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued current policy may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. In considering and reevaluating this policy, we believe it would be appropriate to revise our policy to allow critical care services to be reported when furnished as split (or shared) services. Therefore, we are proposing that critical care visits may be furnished as split (or shared) visits. The proposals described in section II.F.1. of this proposed rule for split (or shared) visits would apply (with one exception discussed below), and service time would be counted for CPT code 99292 in the same way as for prolonged E/M services. In other words, we are proposing that the total critical care service time provided by a physician and NPP in the same group on a given calendar date to a patient would be summed, and the practitioner who furnishes the substantive portion of the cumulative critical care time would report the critical care service(s).

In section II.F.1. of this proposed rule, drawing on the CPT E/M Guidelines, we proposed a list of activities that could count toward total time for purposes of determining the substantive portion. We stated that since critical care services can include additional activities that are bundled into the critical care visits code(s), we are proposing a different listing of qualifying activities for split (or shared) critical care. These qualifying activities are described in prefatory language on pp. 31–32 of the CPT Codebook. Thus, when critical care services are furnished as a split (or shared) visit, we are proposing to define the substantive portion as more than half the cumulative total time in qualifying activities that are included in CPT codes 99291 and 99292. Additionally, the billing practitioner would first report CPT code 99291 and, if 75 or more cumulative total minutes were spent providing critical care, one or more units of CPT code 99292. We would require practitioners to include the proposed split (or shared) visit modifier on the claim, and we are proposing that the documentation and other rules proposed in section II.F.1. of this proposed rule for split (or shared) visits would apply to split critical care services. We note that, in contrast to our proposals regarding concurrent critical care services above, we are proposing that when a critical care service is furnished as a split (or shared) visit, when two or more practitioners spend time jointly meeting with or discussing the patient, the time may be counted only once for purposes of reporting the split (or shared) critical care visit. This proposed policy accords with our proposed policy for all split (or shared) visits. It also accords with the CPT E/M Guidelines stating that, for split (or shared) visits, when two or more individuals jointly meet with or discuss the patient, only the time of one individual should be counted).[32]

We are seeking comment on these proposals to ensure they reflect a clinically appropriate approach, and intend to assess whether we should instead require that an individual physician or NPP directly perform the entirety of each critical care visit. We are seeking comment on this proposal to better understand current clinical practice for critical care, and when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care to a patient.

f. Critical Care Visits and Same-Day Emergency Department, Inpatient or Office/Outpatient Visits

The CPT Codebook states that critical care and other E/M services may be provided to the same patient on the same date by the same individual. However, our general policy as described in the Medicare Claims Processing Manual states that physicians in the same group who are in the same specialty must bill and be paid for services under the PFS as though they were a single physician. If more than one E/M visit is provided on the same day to the same patient by the same physician, or by more than one physician in the same specialty in the same group, only one E/M service may be reported unless the E/M services are for unrelated problems. Instead of billing separately, the physicians should select a level of service representative of the combined visits and submit the appropriate code for that level.[33] This policy is intended to ensure that multiple E/M visits for a patient on a single day are medically necessary and not duplicative. With respect to office/outpatient E/M visits specifically, our current manual instructs, ''As for all other E/M services except where specifically noted, the Medicare Administrative Contractors (MACs) may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems in the office, off campus-outpatient hospital, or on campus-outpatient hospital setting which could not be provided during the same encounter.'' [34] With respect to hospital visits, hospital ED visits, and critical care services furnished on the same day, the Medicare Claims Processing Manual states, ''When a hospital inpatient or office/outpatient E/M service are furnished on a calendar date at which time the patient does not require critical care and the patient subsequently requires critical care both the critical care services (CPT codes 99291 and 99292) and the previous E/M service may be paid on the same date of service. Hospital ED services are not paid for the same date as critical care services when provided by the same physician to the same patient.'' [35]

We are concerned that adopting the CPT rule that critical care and other E/M visits may be furnished to the same patient on the same date by the same practitioner could have unintended consequences for the Medicare program. We have previously expressed concerns that multiple E/M visits by the same practitioner, or by practitioners in the same specialty within a group, on the same day as another E/M service ordinarily would not be medically necessary (83 FR 59639). It is possible that adopting the CPT rule allowing billing for critical care and other E/M

[32] 2021 CPT Codebook (Evaluation and Management (E/M) Services Guidelines), p.7.

[33] Medicare Claims Processing Manual (Pub. 100–02), Chapter 12, Section 30.6.5, *Physicians In Group Practice.*

[34] Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.7.B., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

[35] Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.9.B., available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

visits on the same day, by practitioners in the same group and of the same specialty, could lead to duplicative payment, particularly given the frequently long duration of critical care services, the CPT prefatory language indicating that time spent furnishing critical care may be non-continuous, and the relatively higher valuation of critical care services compared to other E/M services. Thus, we are proposing that no other E/M visit can be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty in the same group.

There are possible alternative approaches to address our concerns about medical necessity and duplicative payment for E/M services furnished to a patient on the same day by the same practitioner or a practitioner in the same group. We have previously considered a Multiple Procedure Payment Reduction (MPPR) for standalone office/outpatient E/M visits that occur on the same day as a procedure to address efficiencies (for example, in preservice and postservice clinician work and PE) that are not accounted for in the current payment rates (83 FR 59639). These visits could be identified on the claim with modifier −25 (significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service) and CMS could assign a reduced payment rate to one of the visits. CMS could also use documentation requirements to support the medical necessity and non-duplicative nature of a claim for critical care services on the same calendar date as another E/M visit provided to a patient by the same practitioner or practitioner of the same specialty in a group. We also recognize that our proposal not to allow an E/M visit to be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty within a group, may be appropriate only in certain clinical situations. For example, it may be possible that a patient would not require critical care services at the time of an ED visit, but then be admitted to the hospital on the same calendar date as the ED visit and require care that meets the definition of critical care services. It may also be possible that the practitioner who furnished the ED visit later provided critical care services to the same patient on the same calendar date. Thus, we are seeking comment on this proposal to better understand clinical practice for critical care, whether and how CMS could pay for E/M services furnished on the same date as critical care services when provided by the same practitioner, or practitioners in the same specialty within a group, while also reducing the potential for duplicative payment.

g. Critical Care Visits and Global Surgery

Critical care services may be needed on the on the same calendar date as a procedure code with a global surgical period. In many cases, preoperative and postoperative critical care visits are included in procedure codes that have a global surgical period. In the CY 2015 PFS final rule, we discussed the challenges of accurately accounting for the number of visits included in the valuation of 10- and 90-day global packages (79 FR 67548, 67582). The 10- and 90-day global packages can include critical care visits. We finalized a policy to change all global periods to 0-day global periods, and to allow separate payment for post-operative E/M visits. Our concerns were based on a number of key points including: The lack of sufficient data on the number of visits typically furnished during the global periods, questions about whether we will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and concerns about how our global payment policies could affect the services that are actually furnished. Section 1848(c)(8)(B) of the Act, which was added by section 523(a) of the Medicare Access and CHIP Reauthorization Act (MACRA), required us to collect data to value surgical services. Because critical care visits are included in some 10- and 90-day global packages, we are proposing to bundle critical care visits with procedure codes that have a global surgical period. We note that this proposal contrasts with the current policy as described in the Medicare Claims Processing Manual which states that critical care visits are unbundled from procedures with a global surgical period as long as the critical care service was unrelated to the procedure.[36] As we have made clear in previous rulemaking, we are continuing to assess values for global surgery procedures (84 FR 2452), including in particular the number and level of preoperative and postoperative visits, which can include critical care services. Because this work is still ongoing, we are proposing to bundle critical care visits with procedure codes that have a global surgical period.

h. Documentation Requirements

Because critical care is a time-based service, we are proposing to require practitioners to document in the medical record the total time that critical care services were provided by each reporting practitioner (not necessarily start and stop times). The documentation would also need to indicate that the services furnished to the patient, including any concurrent care by the practitioners, were medically reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. To support coverage and payment determinations regarding concurrent care, services would need to be sufficiently documented to allow a medical reviewer to determine the role each practitioner played in the patient's care (that is, the condition or conditions for which the practitioner treated the patient). To support coverage and payment determinations regarding split (or shared) critical care services, the documentation requirements proposed above for all split (or shared) E/M visits would also apply to critical care visits (see section II.F. of this proposed rule).

3. Payment for the Services of Teaching Physicians

As part of the CPT office/outpatient E/M visit coding framework that we finalized beginning for CY 2021 (85 FR 84548 through 84574), practitioners can select the office/outpatient E/M visit level to bill, based either on the total time personally spent by the reporting practitioner or MDM. Stakeholders have asked us how teaching physicians who involve residents in furnishing care should consider time spent by the resident in selecting the office/outpatient E/M visit level.

For teaching physicians, section 1842(b) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought.

Regulations regarding PFS payment for teaching physician services are codified in 42 CFR part 415. In general, under § 415.170, payment is made under the PFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician

[36] Pub. 100–04, Medicare Claims Processing Manual, Chapter 12, Section 40.2.9, available on the CMS website.

who is not a resident, or the services are furnished by a resident in the presence of a teaching physician, with exceptions as specified in subsequent regulatory provisions in part 415. Medicare separately pays for the time spent by the resident through direct graduate medical education (GME) under Medicare Part A.

a. General Policy for Evaluation and Management Visits

Under our regulation at § 415.172 and absent a public health emergency (PHE), if a resident participates in a service furnished in a teaching setting, a teaching physician can bill for the service only if they are present for the key or critical portion of the service. For residency training sites that are located outside a metropolitan statistical area, PFS payment may also be made if a teaching physician is present through audio/video real-time communications technology (that is, ''virtual presence''). In the case of E/M services, the teaching physician must be present during the portion of the service that determines the level of service billed.

We are proposing that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. We believe it is appropriate to include only the time of the teaching physician because the Medicare program makes separate payment for the program's share of the resident's graduate medical training program, which includes time spent by a resident furnishing services with a teaching physician, under Medicare Part A. During the PHE, the time of the teaching physician when they are present through audio/video real-time communications technology may also be included in the total time considered for visit level selection. We note that, outside the circumstances of the COVID–19 PHE, the teaching physician presence requirement can be met virtually, through audio/video real-time communications technology, only in residency training sites that are located outside of a metropolitan statistical area.

This proposal is consistent with our previously finalized policy that practitioners can use total time personally spent by the reporting practitioner to select office/outpatient E/M visit level. It is also consistent with our regulation at § 415.172 that states that PFS payment is made when a teaching physician involves a resident in providing care only if the teaching physician is present for the key or critical portions of the service, including the portion that is used to select the visit level.

b. Primary Care Exception Policy

The regulation at § 415.174 sets forth an exception to the conditions for PFS payment for services furnished in teaching settings in the case of certain E/M services furnished in certain primary care centers. Under the so-called ''primary care exception,'' Medicare makes PFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. We expanded the list of services that residents could furnish without the physical presence of the teaching physician for the duration of the PHE to include all levels of an office/outpatient E/M visit, among other services. Upon the conclusion of the PHE, levels 4–5 office/outpatient E/M visits will no longer be included in the primary care exception (85 FR 84585 through 84590).

Section 415.174(a)(3) requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision), and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. Section 415.174(a)(3) also requires that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, and ensure that the services furnished are appropriate.

We are proposing that under the primary care exception, only MDM can be used to select office/outpatient E/M visit level. The intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough to permit a teaching physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. In the context of teaching hospital primary care centers that are staffed by residents and teaching physicians, we believe that MDM would be a more accurate indicator of the complexity of the visit as opposed to time. Because residents are in training, they may need more time than is reflected in the code descriptor to furnish a visit that has a low-level of medical decision making. For example, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20–29 minutes of total time is spent on the date of the encounter*) involves a low level of MDM and between 20–29 minutes of total time. If time was used for level selection instead of MDM, it is possible that residents may need more than 20–29 minutes of time, including any conferring with the teaching physician, to furnish CPT code 99213. Thus, residents may be less efficient relative to a teaching physician in furnishing care.

Office/outpatient E/M visits requiring 30 or more minutes of total time are described by visit levels 4–5. After the expiration of the COVID–19 PHE, office/outpatient levels 4–5 will no longer be included in the primary care exception. In the CY 2021 PFS final rule, we expressed concern that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. We noted that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision-making, the ability to be immediately available to other residents could be compromised, potentially putting patients at risk (85 FR 84586). Thus, to guard against the possibility of residents furnishing visits that are of more than lower and mid-level complexity, we are proposing that only MDM may be used for office/outpatient E/M visit level selection for services furnished by residents under the primary care exception.

We acknowledge that under the new CPT office/outpatient E/M visit coding framework, it is possible that time is an accurate indicator of the complexity of the visit. Thus, we are seeking comment on this proposal, including our assumption that MDM is a more accurate indicator of the appropriate level of the visit relative to time in the context of the primary care exception for services furnished by residents and billed by teaching physicians in primary care centers. We are also seeking comment on whether time is an accurate indicator of the complexity of the visit and how teaching physicians might select office/outpatient E/M visit level using time when directing the care of a patient that is being furnished by a resident in the context of the primary care exception.

G. Billing for Physician Assistant (PA) Services

Under the respective Medicare statutory benefit categories for services of Physician assistants (PAs), nurse practitioners (NPs), and clinical nurse specialists (CNSs), these practitioners are authorized to furnish services that would be physicians' services if they were furnished by a physician, and which they are legally authorized to perform by the state in which the services are furnished; and such services that are furnished incident to the practitioners' professional services (but only if no facility or other provider charges or is paid any amount for the services). Additionally, the payment amount for the services of PAs, NPs, and CNSs, as specified under section 1833(a)(1)(O) of the Act, is equal to 80 percent of the lesser of the practitioner's actual charge or 85 percent of the amount that would be paid to a physician under the PFS. However, while NPs and CNSs are authorized to bill the Medicare program and be paid directly for their professional services, section 1842(b)(6)(C)(i) of the Act has required since the inception of the PA benefit (with a narrow exception not relevant here) that payment for PA services must be made to the PA's employer. Accordingly, our regulation at § 410.74(a)(2)(v) specifies that PA services are covered under Medicare Part B only when billed by the PA's employer. Our regulation that addresses to whom Medicare Part B payment is made, at § 410.150(b)(15), further provides that payment is made to the qualified employer of a PA, and specifies that the PA could furnish services under a W–2 employment relationship, an employer-employee relationship, or as an independent contractor through a 1099 employment relationship. The regulation also specifies that a group of PAs that incorporate to bill for their services is not a qualified employer. Given the statutory requirement that we make payment to the PA's employer, PAs are precluded from directly billing the Medicare program and receiving payment for their services, and do not have the ability to reassign Medicare payment rights for their services to any employer, facility, or billing agent.

Section 403 of the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260, December 27, 2020), amends section 1842(b)(6)(C)(i) of the Act to remove the requirement to make payment for PA services only to the employer of a PA effective January 1, 2022. With the removal of this requirement, PAs will be authorized to bill the Medicare program and be paid directly for their services in the same way that NPs and CNSs do. Effective with this amendment, PAs also may reassign their rights to payment for their services, and may choose to incorporate as a group comprised solely of practitioners in their specialty and bill the Medicare program, in the same way that NPs and CNSs may do. We note that the amendment made by section 403 of the CAA changed only the statutory billing construct for PA services. It neither changed the statutory benefit category for PA services, including the requirement that PA services are performed under physician supervision, at section 1861(s)(2)(K)(i) of the Act, nor did it change the statutory payment percentage applicable to PA services specified in section 1833(a)(1)(O) of the Act.

We are proposing to amend pertinent sections of our regulations to reflect the amendment made by section 403 of the CAA. Specifically, we are proposing to amend § 410.74(a)(2)(v) to specify that the current requirement that PA services must be billed by the PA's employer in order to be covered under Medicare Part B is effective only until January 1, 2022. We are also proposing to amend § 410.150(b) to redesignate the current requirements in paragraph (b)(15) as § 410.150(b)(15)(i), and to amend that paragraph to provide that Medicare payment is made for PA services to the qualified employer of the PA for services furnished prior to January 1, 2022. In § 410.150, we further propose to add a new paragraph (b)(15)(ii) to state that, effective for services furnished on or after January 1, 2022, payment is made to a PA for their professional services, including services and supplies furnished incident to their services. We would conform this new paragraph with the regulation at § 410.150(b)(16) regarding to whom payment is made for NP or CNS services. As such, the proposed new paragraph at § 410.150(b)(15)(ii) would provide that payment will be made to a PA for professional services furnished by a PA in all settings in both rural and non-rural areas; and that payment is made only if no facility or other provider charges or is paid any amount for services furnished by a PA. We also intend to update our program manual instructions to reflect the statutory change made by section 403 of the CAA and the changes to our regulations.

H. Therapy Services

We are implementing the third and final part of the amendments made by section 53107 of the Bipartisan Budget Act (BBA of 2018) (Pub. L. 115–123, February 9, 2018). The BBA of 2018 added a new section 1834(v) of the Act. Section 1834(v)(1) of the Act requires CMS to make a reduced payment for physical therapy and occupational therapy services furnished in whole or in part by physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) at 85 percent of the otherwise applicable Part B payment for the service, effective January 1, 2022.

Section 1834(v)(2) of the Act requires that: (1) By January 1, 2019, CMS must establish a modifier to indicate that a therapy service was furnished in whole or in part by a PTA or OTA; and, (2) beginning January 1, 2020, each claim for a therapy service furnished in whole or in part by a PTA or an OTA must include the modifier. Section 1834(v)(3) of the Act requires CMS to implement these amendments through notice and comment rulemaking.

In the CY 2019 PFS final rule (83 FR 59654 through 59660), we established the CQ and CO modifiers that were required to be used by the billing practitioner or therapy provider to identify therapy services provided in whole or in part by PTAs and OTAs, respectively, beginning January 1, 2020. We require these payment modifiers to be appended on claims for therapy services, alongside the GP and GO therapy modifiers which are used to indicate the services are furnished under a physical therapy or occupational therapy plan of care, respectively. The payment modifiers are defined as follows:

- *CQ modifier:* Physical therapy services furnished in whole or in part by PTAs.
- *CO modifier:* Occupational therapy services furnished in whole or in part by OTAs. In the CY 2019 PFS final rule (83 FR 59654 through 59660), we did not finalize our proposed definition of ''furnished in whole or in part by a PTA or OTA'' as a service for which any minute of a therapeutic service is furnished by a PTA or OTA. Instead, in response to public comments, we finalized a *de minimis* standard under which a service is considered to be furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA.

In the CY 2019 PFS proposed and final rules (83 FR 35850 through 35852, and 83 FR 59654 through 59660, respectively), we explained that the CQ and CO modifiers would not apply to claims for outpatient therapy services that are furnished by, or incident to, the services of, physicians or NPPs including NPs, PAs, and CNSs. This is because our outpatient physical and

occupational therapy services regulations require that the individual who performs outpatient therapy services incident to the services of a physician or NPP must meet the qualifications and standards for a therapist (other than state licensure). As such, only therapists, and not therapy assistants, can perform outpatient therapy services incident to the services of a physician or NPP (83 FR 59655 through 59656); and the modifiers to describe services furnished in whole or in part by a PTA or OTA are not applicable to the claim for a therapy service billed by a physician or NPP incident to their professional services. We indicated that we would add this distinction in the provision of the Medicare Benefit Policy Manual (MBPM) Chapter 15 that discusses therapy services furnished incident to the physician's or NPP's services at section 230.5, as well as the sections that discuss PTA and OTA services at sections 230.1 and 230.2, respectively.

In the CY 2020 PFS proposed and final rules (84 FR 40558 through 40564 and 62702 through 62708, respectively), we explained that the CQ/CO modifiers and the *de minimis* policy would apply to both untimed and timed codes. The untimed codes are evaluation and reevaluation codes, group therapy and supervised modalities, and when these are billed, only one unit is reflected in the ''units'' portion of the claim. When the PTA/OTA provides more than 10 percent of the service, the code is billed with a CQ/CO modifier. For timed codes, that is, those codes defined in 15-minute increments, the services are typically performed in multiple units of the same and/or different codes for a patient on one treatment day. We explained that under our policy, the therapist or therapy assistant needs to find the total time of all these 15-minute timed codes in order to determine the number of units that can be billed for that day. For example, if the PT/OT and/or the PTA/OTA, as appropriate, furnished between 8 minutes through 22 minutes, one unit can be billed; if 23 minutes through 37 minutes are provided, 2 units can be billed; if 38 minutes through 52 minutes are furnished, 3 units can be billed. Once the total number of units to bill is determined, the qualified professional (therapist or assistant) then needs to decide whether the CQ/CO modifier is applicable.

In the CY 2020 PFS proposed rule (84 FR 40558 through 40564), we proposed that the time the PTA/OTA spent together with the PT/OT in performing a service, as well as the time the PTA/OTA spent independent of the PT/OT treating the patient, is considered time for which the service is furnished in whole or in part by the PTA/OTA. As explained in the CY 2020 PFS final rule (84 FR 62702 through 62708), many commenters objected to our proposal to include as time that the therapy service is furnished ''in whole or in part'' by the PTA/OTA both the minutes spent by the PTA/OTA concurrently with and separately from the therapist. These commenters also expressed concerns that this policy would unfairly discount services that are fully furnished by therapists, and in which the therapy assistant supports them while they provide a service. We were persuaded by commenters to finalize a policy to not include as minutes furnished in whole or in part by a PTA/OTA the minutes in which the PTA/OTA worked concurrently with the PT/OT. We agreed with the commenters that when a therapy assistant and therapist furnish care to a patient at the same time, the patient requires both professionals, and this reflects a clinical scenario where the assistant is helping the therapist to provide a highly skilled procedure or one in which both professionals are needed for safety reasons. We modified our proposed regulation text at §§ 410.59 (outpatient occupational therapy), 410.60 (physical therapy), and 410.105 (for PT and OT CORF services) accordingly.

For purposes of deciding whether the 10 percent *de minimis* standard is exceeded, we offered two different ways to compute this.

- *The simple method:* Divide the total of the PTA/OTA + PT/OT minutes by 10, round to the nearest integer then add 1 minute to get the number of minutes needed to exceed the *de minimis* standard at and above which the CQ/CO modifier applies.
- *The percentage method:* Divide the PTA/OTA minutes by the sum of the PTA/OTA and therapist minutes and then multiply this number by 100 to calculate the percentage of the service that involves the PTA/OTA, if this number is greater than 10 percent the CQ/CO modifier applies.

Hypothetical examples of each of these methods are included later in this section. In response to our proposal that all the units of one service needed to be considered when determining if the *de minimis* is applied, commenters requested that we consider each 15-minute unit instead—noting that they would be able to apply the CQ/CO modifier on one claim line for a service that was provided by the PTA/OTA and report another claim line without the CQ/CO for the service provided by the PT/OT. We were persuaded by stakeholders, and finalized a policy under which the *de minimis* standard is applied for each 15-minute unit of a service. This allows the separate reporting, on two different claim lines, of the number of 15-minute units of a code to which the therapy assistant modifiers do not apply, and the number of 15-minute units of a code to which the therapy assistant modifiers do apply. However, we neglected to modify the text of our regulations to reflect this final policy for applying the *de minimis* standard; therefore, we are proposing to revise our regulation text to specify that the *de minimis* rule is applied to each 15-minute unit of a service, rather than to all the units of a service at §§ 410.59(a)(4)(iii)(B), 410.60(a)(4)(iii)(B), and 410.105(d)(3)(ii). The specific proposed revisions are discussed below.

To recap, we finalized a *de minimis* standard to identify when the CQ/CO modifiers apply and when they do not apply as follows:

- Portions of a service furnished by the PTA/OTA independent of the physical therapist/occupational therapist, as applicable, that do not exceed 10 percent of the total service (or 15-minute unit of a service) are not considered to be furnished in whole or in part by a PTA/OTA, so are not subject to the payment reduction;
- Portions of a service that exceed 10 percent of the total service (or 15-minute unit of a service) when furnished by the PTA/OTA independent of the therapist must be reported with the CQ/CO modifier, alongside of the corresponding GP/GO therapy modifier; are considered to be furnished in whole or in part by a PTA/OTA, and are subject to the payment reduction; and
- Portions of a service provided by the PTA/OTA together with the physical therapist/occupational therapist are considered for this purpose to be services provided by the therapist.

In the CY 2020 PFS proposed rule (84 FR 40558 through 40564), we proposed to adopt a documentation requirement that a short phrase or statement must be added to the daily treatment note to explain whether the therapy assistant modifier was or was not appended for each therapy service furnished. We also sought comment on whether it would be appropriate to also require documentation of the minutes spent by the therapist or therapy assistant along with the CQ/CO modifier explanation as a means to avoid possible additional burden associated with a contractor's medical review process conducted for these services. Many commenters stated that: (1) The statute does not require documentation to explain why a

modifier was or was not applied for each code; (2) the proposed documentation requirements are exceedingly burdensome and conflict with the agency's ''Patients over Paperwork Initiative''; (3) the proposed documentation requirement that calls for a narrative phrase in the treatment note and requires documentation of the minutes is duplicative of current requirements that requires adding the total timed code minutes and total treatment time (includes timed and untimed codes) to the daily treatment note; and, (4) the Medicare Benefit Policy Manual (MBPM) already includes extensive documentation requirements. In response to the feedback, we did not finalize the proposed documentation requirement; nor did we finalize a requirement that the therapist and therapy assistant minutes be included in the documentation. Instead, we reminded therapists and therapy providers that correct billing requires sufficient documentation in the medical record to support the codes and units reported on the claim, including those reported with and without an assistant modifier. Further, in agreement with many commenters, we clarified that we would expect the documentation in the medical record to be sufficient to know whether a specific service was furnished independently by a therapist or a therapist assistant, or was furnished ''in part'' by a therapist assistant, in sufficient detail to permit the determination of whether the 10 percent standard was exceeded.

In the CY 2020 PFS proposed rule, we also provided multiple typical clinical billing scenarios to illustrate when the CQ/CO modifier would and would not be applicable. Because these clinical scenarios did not convey our finalized policies as modified in response to public comments, we indicated in the CY 2020 PFS final rule that we would provide further detail regarding the clinical scenario examples to illustrate how to use the therapy assistant modifiers through information we would post on the cms.gov website. We clarified that our revised finalized policy applied generally in the same way as illustrated in those examples, except for the difference in the minutes of time that are counted toward the 10 percent standard (not counting the minutes furnished together by a therapist and therapy assistant), the application of the 10 percent standard to each billed unit of a timed code rather than to all billed units of a timed code, and the billing on two separate claim lines of the units of a timed code to which the therapy assistant modifiers do and do not apply.

In early March 2021, we posted on our Therapy Services website at *https://www.cms.gov/Medicare/Billing/TherapyServices* general guidance on how to assign the CQ/CO modifiers for multiple billing scenarios. In the guidance, we provided general examples for 8 different billing scenarios in which multiple units of 15-minute codes are provided by PTs/OTs and PTAs/OTAs and one billing example that used the untimed code for group therapy performed for equal minutes by a PT and a PTA.

We noted that prior to applying our rules to determine appropriate application of the CQ/CO modifiers, the PTA/OTA or PT/OT first needs to determine how many 15-minute units can be billed in a single treatment day for a patient. For information on this topic, we referred readers to the chart in section 20.2.C of Chapter 5 of the Medicare Claims Processing Manual (MCPM) that describes how to count minutes for timed codes defined by 15-minute units, since the therapist or assistant should use the same counting rule, commonly known as the ''8-minute rule,'' that they have used previously.

Once the therapist or therapy assistant has identified the number of 15-minute units that can be billed for a patient on a single treatment day, we provided the following information to clarify how to apply our policy for application of the CQ and CO modifiers, as follows:

Step 1. Identify the Timed HCPCS Codes Furnished for 15 Minutes or More: List the code numbers of each of the services furnished along with the number of minutes in total done by the PT, PTA, OT, or OTA. When a PT, PTA, OT, or OTA provides at least 15 minutes and less than 30 minutes of a service on a single treatment day, assign 1 unit; when multiples of 15 minutes are furnished, for example, 30 minutes (assign 2 units) and 45 minutes (assign 3 units), etc. This needs to be the first step whenever it is applicable to the billing scenario. When any of these services, that is, full 15-minute increments, are provided by a PTA/OTA, the CQ/CO modifiers apply.

Step 2. Identify Services for Which the PT/OT and PTA/OTA Provide Minutes of the Same HCPCS Code: After applying Step 1, where applicable, identify any minutes (including remaining minutes from Step 1) performed by a PT/OT and PTA/OTA for the same service/code. Add the minutes furnished by the PT/OT and the PTA/OTA together, then divide the total by 10 and round to the nearest integer—this is the 10 percent *de minimis* time standard. Then add 1 minute to get the fewest number of minutes performed by the PTA/OTA that would exceed the 10 percent time standard for that service—if the PTA/OTA minutes meet or exceed this number, the CQ/CO modifier would be appended. This is the ''simple'' method for calculating the *de minimis* number of minutes.

Step 3. Identify Services Where the PT/OT and PTA/OTA Furnish Services of Two Different Timed HCPCS Codes: After applying Step 1 for each service, compare the remaining minutes furnished by the PT/OT for one service with the remaining minutes furnished by the PTA/OTA for a different service. Assign the CQ/CO modifier to the service provided by the PTA/OTA when the time they spent is greater than the time spent by the PT/OT performing the different service. The CQ/CO modifier does not apply when the minutes spent delivering a service by the PT/OT are greater than the minutes spent by the PTA/OTA delivering a different service.

Step 4. Identify the Different HCPCS Codes Where the PT/OT and the PTA/OTA Each Independently Furnish the Same Number of Minutes: Once Step 1 is completed for each service (when applicable), and when the remaining minutes for each service—one provided by the PT/OT and the other provided by the PTA/OTA—are the same, either service may be billed. If the service provided by the PT/OT is billed, the CQ/CO modifier does not apply. However, if the service provided by the PTA/OTA is billed, the CQ/CO modifier does apply.

The below two examples are taken from our guidance on the CMS website. These are examples of when the PT and PTA provide minutes of the same service:

Example #1

PTA—23 minutes 97110
PT—13 minutes 97110
PT—30 minutes 97140

Total = 66 minutes—qualifies for billing 4 units (53 minutes through 67 minutes).

Billing Explanation:

- *First Step:* Assign units to services based on those that have at least 15 minutes or codes that were provided in multiples of 15 minutes. For 97110, assign one unit of 97110 with the CQ modifier because the PTA furnished at least 15 minutes of 97110 (therapeutic exercise). Then, assign two units of 97140 without the modifier, because the PT furnished the full 30 minutes of manual therapy.
- *Second Step:* Determine if the PTA furnished more than 10 percent of the remaining minutes of the 97110 service. To do this via the simple method: Add

the PTA's 8 remaining minutes to the PT's 13 minutes for a total time of 21 minutes. Divide the total by 10 to get 2.1 minutes and round to the nearest integer, which is 2 minutes (the 10 percent time standard for this service). Add 1 minute to find the threshold number of minutes that would exceed the *de minimis* standard, which in this example is 3 minutes. Using the percentage method, divide the PTA's remaining 8 minutes by the total 21 minutes of the service (8 PTA + 13 PT = 21 minutes) to get 0.38, then multiply the result × 100 = 38 percent.

Final Step: Because 8 minutes meets or exceeds the 3-minute threshold, and 38 percent is greater than 10 percent, a second unit of 97110 is billed with the CQ modifier.

Example #2

PTA—19 minutes of 97110
PT—10 minutes of 97110

Total = 29 minutes—two units of 97110 can be billed (23 minutes through 37 minutes).

Billing Explanation:

- *First Step:* Bill one unit of 97110 with the CQ modifier because a full 15 minutes was provided by the PTA, with 4 minutes remaining.
- *Second Step:* Determine if the PTA's 4 remaining minutes exceed the 10 percent *de minimis* standard. Simple method: Add together the PTA's 4 remaining minutes and the 10 PT minutes to get the total time of 14 minutes and divide by ten to get 1.4 minutes and round to the nearest integer = 1 minute to get the 10 percent *de minimis* standard. Then add 1 minute to get a threshold minimum of 2 minutes for PTA time. If the PTA minutes are at or above the threshold, the CQ modifier applies. Percentage method: Divide the PTA's 4 remaining minutes by the total time of 14 to get 0.29 then multiply by 100 = 29 percent. If the resulting percentage is greater than 10 percent, the PTA modifier applies.
- *Final Step:* Bill another unit of 97110 with the CQ modifier since 4 minutes is greater than the 2-minute threshold minimum and 29 percent is greater than 10 percent.

After reviewing the information posted on the CMS Therapy Services web page, therapy stakeholders reached out to CMS to express concern that certain aspects of the billing scenarios described in the guidance contradict their interpretation of our *de minimis* policy, especially as it applies to a final unit of a multiple-unit timed service. The therapy stakeholders suggested that the guidance we offered would lead to confusion for the same-service billing scenarios (including examples #1 and #2 above). We consider the unit of measure for a timed therapy service code to be 15 minutes. In billing scenarios with multiple units, we would consider the combined time for same or different services in 15-minute unit increments.

The stakeholders agree that the *de minimis* standard is applied to the last unit of a timed therapy service code in two separate cases. The first case happens when the PTA/OTA and the PT/OT each furnish less than 8 minutes for that final unit of a service. For example, if the PTA/OTA provided 7 minutes and the PT/OT furnished 5 minutes—using the simple method: 12 minutes divided by 10 equals 1.2, rounded to the nearest integer is 1, plus 1 equals 2—if the PTA/OTA provides 2 or more minutes, the CQ/CO modifier is applied. The second case occurs when the PTA/OTA provides 8 or more minutes and the PT/OT furnishes less than 8 minutes—in which event, the *de minimis* standard is exceeded and the CQ/CO modifier is applied.

We note that the therapy stakeholders' interpretation of when the *de minimis* policy applies for a final 15-minute unit of a multiple unit timed service is based on what is commonly termed the ''8-minute rule'' which recognizes a unit of a 15-minute timed therapy service code as 8 minutes (more than the midpoint of the service or 7.5 minutes), but only when it applies to the final unit billed. Applied to the above two examples, the stakeholders informed us that they believe the second unit of CPT code 97110 in both examples should not be billed with an assistant modifier because the therapist provided enough minutes of the service on their own, that is, 8 minutes or more, to bill for the last unit without the assistant's additional minutes. The stakeholders indicated that the therapist would have a financial incentive to not have the PTA/OTA provide the additional minutes at all if the CQ or CO modifier would apply. We note that, in addition to the two cases discussed above, there is another billing scenario to address in the context of our *de minimis* policy—specifically, where the PT/OT and PTA/OTA each furnish between 9 and 14 minutes of a 15-minute timed service when the total time of therapy services furnished in combination by the PTA/OTA and PT/OT is at least 23 but no more than 28 minutes, and there are two remaining units left to be billed. These ''two remaining unit'' cases with time ranges between 9 and 14 minutes include the following PTA/OTA:PT/OT (or vice versa) time splits: 9:14, 10:13, 11:12, 12:12, 12:13, 12:14, 13:13; 13:14; and 14:14.

We believe that the stakeholder's interpretation of the *de minimis* standard is not consistent with the *de minimis* policy we finalized in the CY 2020 PFS final rule (84 FR 62702 through 62708). However, in working through the billing scenarios with the stakeholders, we identified where we could make refinements to our policy to address some of the confusion and concerns expressed by stakeholders and to address the ''two remaining unit'' cases noted above. These refinements may also avoid implementing a payment policy that could be perceived to penalize the provision of additional care by a therapy assistant when those minutes of service would lead to a reduced payment for a unit of a service. The stakeholders criticized the finalized *de minimis* policy because they believed it provides an inherent financial incentive for the therapist to ensure that PTAs/OTAs provide services in exactly 15-minute intervals—to avoid any leftover PTA/OTA minutes that could necessitate application of the CQ/CO modifier, and reduced payment, for the service that the therapist is also providing—without regard to the clinical needs of the individual patient. The stakeholders suggested that if we were to recognize their ''8-minute rule'' and recommended policy, we would remove the incentive for the therapist to avoid providing appropriate minutes of therapy services performed by the PTA/OTA.

To address the concerns expressed by the stakeholders and the ''two remaining unit'' cases we identified in our review, we propose to modify our existing policy, specifically for billing scenarios when only one unit of a timed therapy service remains to be billed (the majority of all billing scenarios) and the ''two remaining unit'' cases described above. As shown in Table 19, this proposal would require application of the CQ/CO modifier when the PTA/OTA provides at least 8 minutes or more and the PT/OT provides less than 8 minutes of the service; or, when both the PT/OT and the PTA/OTA provide less than 8 minutes of the same service.

TABLE 19: Billing Scenario Examples Where CQ/CO Modifier Applies

	Billing Scenario	Stakeholders' Rules
Scenario 1	PT/OT (6 minutes) + PTA/OTA (8 minutes) - for a total of 14 minutes.	The PTA/OTA provided 8 minutes or more and the PT/OT provided less than 8 minutes; therefore, the *de minimis* standard is exceeded. Bill with the CQ/CO modifier.
Scenario 2	PT (5 minutes) + PTA/OTA (5 minutes) - for a total of 10 minutes.	Both the PT/OT and the PTA/OTA provided less than 8 minutes; so the *de minimis* standard is exceeded. Bill with the CQ/CO modifier

Under this proposed modification, the CQ/CO modifier would not apply when the PT/OT furnishes 8 minutes or more, or both the PT/OT and the PTA/OTA furnish 8 minutes or more, of a timed service. This proposed ''midpoint rule'' policy was suggested to us by the therapy stakeholders. We agree that since, in this circumstance, the PT/OT provided enough minutes of the service on their own to bill the last unit of the service, the additional minutes of service performed by the PTA/OTA are not material, and thus, should be disregarded, as shown in the examples in Table 20.

TABLE 20: Billing Scenario Examples Where the "Midpoint Rule" Applies

	Billing Scenario	Therapy Stakeholder Midpoint Rule
Scenario 1	PT (8 minutes) + PTA/OTA (7 minutes) — for a total of 15 minutes.	The PT/OT bills without the CQ/CO modifier because they provided enough minutes on their own (8 minutes or more) without the PTA's/OTA's time to bill the one unit. Disregard PTA/OTA minutes.
Scenario 2	PT (11 minutes) + PTA/OTA (11 minutes) - for a total of 22 minutes.	The PT/OT bills without the CQ/CO modifier because they provided enough minutes on their own (8 minutes or more) without the PTA's/OTA's time to bill the one unit. Disregard PTA/OTA minutes.

With these proposed policy adjustments, the CQ/CO modifiers apply when the PTA/OTA provides all the minutes of a timed service, and to some services (as illustrated in Table 19) when the PTA/OTA and PT/OT each, independent of the other, furnish portions of the same timed service. The CQ/CO modifiers also apply if the portion of an untimed code furnished by the PTA/OTA exceeds the *de minimis* standard. The CQ/CO modifiers do not apply when the PTA/OTA and the PT/OT furnish different services. Time spent by the PT/OT and PTA/OTA providing services together is considered time spent by the PT/OT for purposes of applying the *de minimis* standard. Finally, we propose to modify our policy so that the CQ/CO modifiers would not apply when the PT/OT provides enough minutes of the service on their own to bill for the last unit of a timed service, (more minutes than the midpoint or 8 minutes of a 15-minute timed code) regardless of any additional minutes for the service provided by the PTA/OTA.

Examples of Billing Scenarios using the CQ/CO modifiers when the *de minimis* standard applies, and the proposed policy for the last billed unit of a service:

Example #A:

PTA—10 minutes of 97110
PT—5 minutes of 97110

Total = 15 minutes—qualifies to bill one 15-minute unit (8 minute to 22 minutes).

Analysis: Bill one unit of 97110 with the CQ modifier because the PTA provided 8 minutes or more and the PT provided less than 8 minutes. The *de minimis* standard applies in these cases.

Example #B:

PTA—5 minutes of 97110
PT—6 minutes of 97110

Total = 11 minutes—qualifies to bill one 15-minute unit (8 minute through 22 minutes).

Analysis: Bill one unit of 97110 with the CQ modifier because the PTA and the PT both provided less than 8 minutes. In this case, the PT provided 6 minutes and the PTA furnished 5 minutes independent of each other. The *de minimis* standard applies in these cases.

Example #C:

PTA–22 minutes of 97110
PT—23 minutes of 97110

Total = 45 minutes—qualifies to bill three 15-minute units (38 minutes through 52 minutes).

Analysis:

- Apply Step One of the general policy rules and bill one unit of 97110 with the CQ modifier because the PTA provided 15 full minutes with 7 minutes remaining.
- Apply Step One to the PT's 23 minutes and bill one unit without the assistant modifier with 8 minutes remaining.
- The third unit of 97110 is billed without the assistant modifier because the therapist provided enough minutes (8 or more minutes) without the PTAs minutes to bill the final unit.

Example #D—also see the below regulatory proposal using this 'two remaining unit' example.

PT—12 minutes of 97110
PTA—14 minutes of 97110
PT—20 minutes of 97140

Total = 46 minutes—qualifies to bill three units (38 minutes through 52 minutes).

Analysis:

• Apply Step One of the general policy rules and bill one unit of 97140 without the CQ modifier because the PT provided 15 full minutes of one unit with 5 minutes remaining.

• Two units remain to be billed and the PT and the PTA each provided between 9 and 14 minutes independent of one another with a total time between 23 and 28 minutes—in these ''two remaining unit'' scenarios, one unit is billed with the CQ modifier for the PTA and the other unit is billed without it for the PT.

• The PT's 5 remaining minutes of 97140 are counted towards the total timed minutes but are not billable in this scenario.

Example #E

OTA—11 minutes of 97535
OT—11 minutes of 97530

Total = 22 minutes—qualifies to bill one (1) unit (8 minutes through 22 minutes).

Billing Analysis:

Since two different services were furnished for an equal number of minutes—the ''tie-breaker'' scenario applies. Either code 97530 by the OT or code 97535 by the OTA can be billed in accordance with a billing example in the MCPM, Chapter 5, section 20.2.C. Either one unit of 97530 is billed without the CO modifier or one unit of 97535 is billed with the CO modifier.

Example #F: Untimed code—1 unit is billed for all untimed codes including evaluations, reevaluations, supervised modalities, and group therapy.

OTA—20 minutes 97150 independent of the OT
OT—20 minutes 97150 independent of the OTA

Total = 40 minutes of Group Therapy = 1 unit of 97150 is billed for each group member.

Billing Analysis: One unit of group therapy 97150 is billed with the CO modifier because the OTA provided more than the 10 percent time standard in this example. Either method can be used to determine if the OTA's time exceeded the 10 percent time standard for this clinical scenario, see below:

• *The simple method:* First add the OTA's 20 minutes to the OT's 20 minutes to get 40, then divide by 10 to get 4.0 and add 1 to equal 5 minutes. The OTA's 20 minutes is equal to or greater than 5 minutes so the CO modifier is required on the claim.

• *The percentage method:* Divide the number of minutes that an OTA independently furnished a service by the total number of minutes the service was furnished as a whole—20 divided by 40 equals 0.50. Then multiple by 100 to get 50 percent, which is greater than 10 percent. The CO modifier is applied to 97150.

• *Tie breaker:* The tie breaker does not apply in this scenario because the example does not contain two different timed codes described in 15-minute intervals. For ''tie breaker'' see Example #F above.

As noted above and illustrated in Example #D, there are a finite number of cases where there are two 15-minute units left to bill. In these ''two remaining unit'' cases, the PTA/OTA and the PT/OT each provide between 9 and 14 minutes with a total time of at least 23 minutes through 28 minutes. Under our proposed policy, one unit of the service would be billed with the CQ/CO modifier for the minutes furnished by the PTA/OTA (who furnished between 9 and 14 minutes of the service), and one unit would be billed without the CQ/CO modifier for the service provided by the PT/OT (who also furnished between 9 and 14 minutes of the same service). This is because the PTA/OTA and the PT/OT each independently furnished part of each unit of the same service, and these cases are not addressed by the proposed midpoint rule that would apply when there is only one single unit left to bill. We are proposing to amend our regulation to address the scenario where there are two remaining 15-minute units of the same service for which the PTA/OTA and the PT/OT each provided between 9 and 14 minutes with a total time of at least 23 minutes and no more than 28 minutes. In this scenario, we propose that one unit of the service would be billed with the CQ/CO modifier and the other unit of the service would be billed without the assistant modifier. We are proposing to add this policy to our regulations at §§ 410.59(a)(4)(v) and 410.60(a)(4)(v) for outpatient occupational therapy and physical therapy services, respectively and at § 410.105(d)(3)(iv) for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

As noted above, when we finalized the policy to consider each 15-minute unit of a service for purposes of determining whether the de minimis standard applies, we neglected to revise our regulations at §§ 410.59, 410.60 and 410.105 to reflect this change. As such, we are proposing to amend the regulations at §§ 410.59(a)(4)(iii)(B) and 410.60(a)(4)(iii)(B) for outpatient occupational therapy and physical therapy services, respectively, and at § 410.105(d)(3)(ii) for CORF services to specify that we consider a service to be furnished in part by a PTA or an OTA when the PTA/OTA furnishes a portion of a service, or in the case of a 15-minute timed code, a portion of a unit of a service, separately from the portion of the service or unit of service furnished by the therapist such that the minutes for that portion of a service or a unit of a service furnished by the PTA/OTA exceed 10 percent of the total minutes for that service or unit of a service.

To accommodate the proposed refinement of the de minimis policy, we are proposing to amend the same regulations at §§ 410.59(a)(4)(iv) and 410.60(a)(4)(iv) for outpatient occupational therapy and physical therapy services, respectively, and at § 410.105(d)(3)(iii) for CORF services to provide that, for the final 15-minute unit billed for a patient for a date of service, when the PT/OT provides more than the midpoint (at least 8 minutes) of a service such that they could bill for the service without any additional minutes being furnished by the PTA/OTA, the service may be billed without a CQ or CO modifier, and any remaining minutes of service furnished by the PTA/OTA are considered immaterial.

Beginning January 1, 2022, therapy services furnished in whole or in part by a PTA or OTA will be identified based on the inclusion by the billing therapy services provider (whether a therapist in private practice or therapy provider) of the CQ or CO modifier, respectively, on claim lines for therapy services, and the payment for those services will be adjusted as required by section 1834(v)(1) of the Act. Per our usual system update process, we plan to issue instructions in a change request to prepare our shared systems and Medicare Administrative Contractors (MACs) to pay the reduced amount for therapy services furnished in whole or in part by a PTA or OTA. We will issue an MLN article once the CR is released, after the CY 2022 PFS final rule is issued.

We are seeking comment on all of our proposals.

I. Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021, Waiving Medicare Coinsurance for

Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. The reduced coinsurance will be phased-in beginning January 1, 2022. Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance.

Section 1861(pp) of the Act defines ''colorectal cancer screening tests'' and, under sections 1861(pp)(1)(B) and (C) of the Act, identifies ''screening flexible sigmoidoscopy'' and ''screening colonoscopy'' as two of the recognized procedures. During the course of either one of these two procedures, removal of tissue or other matter may become necessary for diagnostic purposes. Among other things, section 1861(pp)(1)(D) of the Act authorizes the Secretary to include in the definition other tests or procedures and modifications to the tests and procedures described under this subsection, with such frequency and payment limits as the Secretary determines appropriate, in consultation with appropriate organizations. Section 1861(s)(2)(R) of the Act includes colorectal cancer screening tests in the definition of the medical and other health services that fall within the scope of Medicare Part B benefits described in section 1832(a)(1) of the Act. Section 1861(ddd)(3) of the Act includes colorectal cancer screening tests within the definition of ''preventive services.'' In addition, section 1833(a)(1)(Y) of the Act provides for payment for a preventive service under the PFS at 100 percent of the lesser of the actual charge or the fee schedule amount for these colorectal cancer screening tests, and under the OPPS at 100 percent of the OPPS payment amount, when the preventive service is recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. As such, there is no beneficiary coinsurance for recommended colorectal cancer screening tests as defined in section 1861(pp)(1) of the Act.

Under these statutory provisions, we have issued regulations governing payment for colorectal cancer screening tests at § 410.152(l)(5). We pay 100 percent of the Medicare payment amount established under the applicable payment methodology for the setting for providers and suppliers, and beneficiaries are not required to pay Part B coinsurance for colorectal cancer screening tests (except for barium enemas, which are not recommended by the USPSTF with a grade of A or B).[37]

In addition to colorectal cancer screening tests, which typically are furnished to patients in the absence of signs or symptoms of illness or injury, Medicare also covers various diagnostic tests (see § 410.32). In general, diagnostic tests must be ordered by the physician or practitioner who is treating the beneficiary and who uses the results of the diagnostic test in the management of the patient's specific medical condition. Under Part B, Medicare may cover flexible sigmoidoscopies and colonoscopies as diagnostic tests when those tests are reasonable and necessary as specified in section 1862(a)(1)(A) of the Act. When these services are furnished as diagnostic tests rather than as screening tests, patients are responsible for the Part B coinsurance (20 or 25 percent depending upon the setting) associated with these services.

We define colorectal cancer screening tests in our regulation at § 410.37(a)(1) to include ''flexible screening sigmoidoscopies'' and ''screening colonoscopies, including anesthesia furnished in conjunction with the service.'' Under our current regulations, we exclude from the definition of colorectal screening services, colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure. The exclusion of these services from the definition of colorectal cancer screening tests is based upon longstanding provisions under sections 1834(d)(2)(D) and (d)(3)(D) of the Act dealing with the detection of lesions or growths during procedures (see CY 1998 PFS final rule at 62 FR 59048, 59082 for a more detailed explanation).

Prior to the enactment of section 122 of the CAA, section 1834(d)(2)(D) of the Act provided that if, during the course of a screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening flexible sigmoidoscopy, but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal. Similarly, prior to the recent legislative change, section 1834(d)(3)(D) of the Act provided that if, during the course of a screening colonoscopy, a lesion or growth is detected that results in a biopsy or removal of the lesion or growth, payment under Medicare Part B shall not be made for the screening colonoscopy but shall be made for the procedure classified as a colonoscopy with such biopsy or removal. In these situations, Medicare pays for the flexible sigmoidoscopy and colonoscopy tests as diagnostic tests rather than as screening tests and the 100 percent payment rate for recommended preventive services under section 1833(a)(1)(Y) of the Act, as codified in our regulation at § 410.152(l)(5), has not applied. As such, beneficiaries currently are responsible for the usual coinsurance that applies to the services (20 or 25 percent of the cost of the services depending upon the setting).

Under section 1833(b) of the Act, before making payment under Medicare Part B for expenses incurred by a beneficiary for covered Part B services, beneficiaries must first meet the applicable deductible for the year. Section 4104 of the Affordable Care Act (that is, the Patient Protection and Affordable Care Act (Pub L. 111–148, March 23, 2010), and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, March 30, 2010), collectively referred to as the ''Affordable Care Act'') amended section 1833(b)(1) of the Act to make the deductible inapplicable to expenses incurred for certain preventive services that are recommended with a grade of A or B by the USPSTF, including colorectal cancer screening tests as defined in section 1861(pp) of the Act. Section 4104 of the Affordable Care Act also added a sentence at the end of section 1833(b)(1) of the Act specifying that the exception to the deductible shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. Although amendments made by the Affordable Care Act addressed the applicability of the deductible in the case of a colorectal cancer screening test that involves biopsy or tissue removal, they did not alter the coinsurance provision in section 1833(a) of the Act for such procedures. Public commenters encouraged the agency to eliminate the coinsurance in these circumstances;

[37] We refer readers to the CY 2022 OPPS proposed rule for a detailed discussion of Changes to Beneficiary Coinsurance for Colorectal Cancer Screening Tests in outpatient and ambulatory surgical settings.

however, the agency found that statute did not provide for elimination of the coinsurance (75 FR 73170 at 73431).

Beneficiaries have continued to contact us noting their concern that a coinsurance percentage applies (20 or 25 percent depending upon the setting) under circumstances where they expected to receive only a colorectal screening test to which coinsurance does not apply. Instead, these beneficiaries received what Medicare considers to be a diagnostic procedure because, for example, polyps were discovered and removed during the procedure. Similarly, physicians have expressed concern about the reactions of beneficiaries when they are informed that they will be responsible for coinsurance if polyps are discovered and removed during a procedure that they had expected to be a screening procedure to which coinsurance does not apply.

Section 122 of the CAA addresses this coinsurance issue by successively reducing, over a period of years, the percentage amount of coinsurance for which the beneficiary is responsible. Ultimately, for services furnished on or after January 1, 2030, the coinsurance will be zero.

To implement the amendments made by section 122 of the CAA, we are proposing to modify our regulations to reflect the changes to Medicare statute. As amended, the statute effectively provides that, for services furnished on or after January 1, 2022, a flexible sigmoidoscopy or a colonoscopy can be considered a screening flexible sigmoidoscopy or a screening colonoscopy test even if an additional procedure is furnished to remove tissue or other matter during the screening test. Specifically, section 122(a)(3) of the CAA added a sentence to the end of section 1833(a) of the Act to include as colorectal screening tests described in section 1833(a)(1)(Y) of the Act, a colorectal cancer screening test, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. We note that only flexible screening sigmoidoscopies and screening colonoscopies are recognized currently as colorectal cancer screening tests that might involve removal of tissue or other matter. This new sentence added under section 1833(a) of the Act uses the same language that was used to amend the statute at section 1833(b)(1) of the Act and to broaden the scope of colorectal cancer screening tests to which a deductible does not apply. Section 122(b)(1) of the CAA then limits application of the 100 percent Medicare payment rate (that is, no beneficiary coinsurance) under section 1833(a)(1)(Y) of the Act for the additional colorectal cancer screening tests (those that are not screening tests ''but for'' the new sentence at the end of section 1833(a) of the Act) by making payment for them subject to a new section 1833(dd) of the Act. Section 1833(dd) of the Act provides for a series of increases in the Medicare payment rate percentage for those services over successive periods of years through CY 2029. Thereafter, section 1833(dd) of the Act has no effect, so payment for all colorectal cancer screening tests would be made at 100 percent under section 1833(a)(1)(Y) of the Act.

To codify the amendments made by section 122 of the CAA in our regulations, we are proposing to make two modifications to current regulations.

At § 410.37, we propose to modify our regulation where we define conditions for and limitations on coverage for colorectal cancer screening tests by adding a new paragraph (j). That paragraph would provide that, effective January 1, 2022, when a planned colorectal cancer screening test, that is, screening flexible sigmoidoscopy or screening colonoscopy test, requires a related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter as the screening test, it is considered to be a colorectal cancer screening test.

At § 410.152(l)(5), we also propose to modify our regulation. Here we describe payment for colorectal cancer screening tests. Effective January 1, 2022, we propose to provide for an increase in the Medicare payment percentage that is phased in over time. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases. We propose to revise § 410.152(l)(5) to provide that Medicare payment in a specified year is equal to a specified percent of the lesser of the actual charge for the service or the amount determined under the fee schedule that applies to the test. The phased in Medicare payment percentages for colorectal cancer screening services described in the proposed regulation at § 410.37(j) (and the corresponding reduction in coinsurance) are as follows:

- 80 percent payment for services furnished during CY 2022 (with coinsurance equal to 20 percent);
- 85 percent payment for services furnished during CY 2023 through CY 2026 (with coinsurance equal to 15 percent);
- 90 percent payment for services furnished during CY 2027 through CY 2029 (with coinsurance equal to 10 percent); and
- 100 percent payment for services furnished from CY 2030 onward (with coinsurance equal to zero percent).

Thus, between CYs 2022 and 2030, the coinsurance required of Medicare beneficiaries for planned colorectal cancer screening tests that result in additional procedures furnished in the same clinical encounter will be reduced over time from the current 20 or 25 percent to zero percent in CY 2030 and will remain at zero percent for these services furnished beginning in CY 2030 and thereafter.

J. Vaccine Administration Services: Comment Solicitation: Medicare Payments for Administering Preventive Vaccines

On January 31, 2020, under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (the Secretary) determined that a public health emergency (PHE) as a result of confirmed cases of 2019 Novel Coronavirus exists nationwide and has existed since January 27, 2020 (hereafter referred to as the PHE for COVID–19). The Secretary has since renewed this declaration for successive 90-day periods, the latest on April 15, 2021.

The PHE for COVID–19 has reinforced the important and positive impact that preventive vaccines can have on the health of Medicare beneficiaries and the broader public. At the time of publishing this proposed rule, the PHE for COVID–19 declaration is still in effect and the United States is in the middle of a national effort to vaccinate as many people against COVID–19 as quickly as possible. This national effort has at least temporarily altered the landscape for vaccines and vaccine administration by, for example, encouraging existing providers and suppliers to dramatically expand their vaccination capabilities and by encouraging new (and new types) of providers and suppliers to furnish vaccines.

Over the past several years, stakeholders have expressed concerns about the reduction in Medicare payment rates for the service to administer preventive vaccines covered by Medicare Part B under section 1861(s)(10) of the Act, including the influenza, pneumococcal, and hepatitis B virus (HBV) vaccines. In the last two PFS rulemaking cycles (that is, for CY 2020 and CY 2021), we have attempted

to address some of these concerns and these efforts are discussed in more detail below. However, CY 2021 payment rates for administration of these vaccines by suppliers including physicians, NPPs, and mass immunizers remain the same as in CY 2019: A national average rate of $16.94, which is geographically adjusted. In this section, we are seeking feedback on how we should update the payment rate for administration of these preventive vaccines under Medicare Part B.

1. Medicare Part B Payment for Vaccines

Under section 1861(s)(10) of the Act, Medicare Part B covers both the vaccine and its administration for the preventive vaccines specified—the influenza, pneumococcal, HBV, and COVID–19 vaccines. Under sections 1833(a)(1)(B) and (b)(1) of the Act, there is no applicable beneficiary coinsurance, and the annual Part B deductible does not apply for these vaccinations or the services to administer them. In CY 2021, payment for these vaccines is based on 95 percent of the Average Wholesale Price (AWP) for a particular vaccine product except where furnished in the settings for which payment is based on reasonable cost, such as a hospital outpatient department, rural health clinic (RHC), or federally qualified health center (FQHC). For example, for the 2020–2021 influenza season, payment limits for adult influenza vaccine products range from about $19 to $61 per adult dose. We note that most other preventive vaccines not specified for Medicare Part B coverage under section 1861(s)(10) of the Act, such as the shingles vaccine, are covered and paid for under Medicare Part D.

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) added the COVID–19 vaccine and its administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. To implement this section, we issued an interim final rule with comment period (November 4th COVID–19 IFC (85 FR 71145 through 71150)) which established that payments for COVID–19 vaccines and vaccine administration would be made in the same manner as payments for the influenza and pneumococcal vaccines. The IFC specifically amended §§ 414.707(a)(2)(iii) and 414.904(e)(1) to include the COVID–19 vaccine in the list of vaccines with payment limits calculated using 95 percent of the AWP (85 FR 71147). We note that Medicare does not pay providers and suppliers for the vaccine product when the federal government purchases it and gives it to the provider or suppliers for free, as has been the case for all COVID–19 vaccines as of the publication of this proposed rule.

We note that the vaccine administration services described under 1861(s)(10) of the Act are not technically valued or paid under the PFS, as they are not included within the statutory definition of physicians' services in section 1848(j)(3) of the Act. Despite this, we have historically based payment rates for the administration of these preventive vaccines by suppliers such as physicians, NPPs, and mass immunizers on an evaluation of the resource costs involved in furnishing the service, which is similar to the methodology that we use to establish payment rates for the PFS. We note further that we also assign a payment rate for administering these preventive vaccines under the Outpatient Prospective Payment System (OPPS), and those payment rates are for hospitals and home health agencies for preventive vaccine administration. Certain other types of providers and suppliers, such as RHCs, FQHCs and critical access hospitals (CAHs), are paid based on reasonable cost for vaccine administration. We also note that these payments are geographically adjusted based on the provider's wage index.

As discussed in the CY 2021 PFS proposed rule (85 CFR 50162), many stakeholders raised concerns about the reductions in payment rates for the preventive vaccine administration services that had occurred over the past several years. We generally have established payment rates for the three Healthcare Common Procedural Coding System (HCPCS) codes G0008, G0009, and G0010—which describe the services to administer an influenza, pneumococcal and HBV vaccines, respectively, based on a direct crosswalk to the PFS payment rate for CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Because we proposed and finalized reductions in valuation for that code for CY 2018, the payment rate for the vaccine administration codes was concurrently reduced. Further, because the reduction in RVUs for CPT code 96372 was significant enough to be required to be phased in over several years under section 1848(c)(7) of the Act, the reductions in overall valuation for the vaccine administration codes were likewise subject to reductions over several years. As noted in Table 21, the national payment rate for administering these preventive vaccines has declined more than 30 percent since 2015.

TABLE 21: Payment Rates for influenza, pneumococcal and HBV vaccine Administration Services (CY 2015 – CY 2021)

Year	National Payment Rate for G0008, G0009, G0010
2015	$25.51[1]
2016	$25.42
2017	$25.84
2018	$20.88
2019	$16.94
2020	$16.94[2]
2021	$16.94[3]

[1] We note that there were technically two national payment rates in 2015 due to legislation passed mid-year, although the payment amount for G0008, G0009 and G0010 only changed during the year by roughly $0.20.

[2] Frozen to 2019 rate through rulemaking (PFS).

[3] Frozen to 2019 rate through rulemaking (PFS).

We have attempted to address the reduction in payment rates for these vaccine administration HCPCS codes in the last two PFS rulemaking cycles. In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource costs are reflected in the valuation of the immunization administration services that are used to deliver these vaccines, and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008, G0009 and G0010.

In the CY 2021 PFS proposed rule, we proposed to crosswalk G0008, G0009 and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*) (85 FR 50163). In the proposed rule, we noted that CPT code 36000 is a service with a similar clinical vignette, and that the additional clinical labor, supply, and equipment resources associated with furnishing CPT code 36000 were similar to costs associated with these vaccine administration codes. We also noted that this crosswalk would have resulted in payment rates for vaccine administration services at a rate that is approximately the same as the CY 2017 rate (as noted in Table 21) that was in place prior to the revaluation of CPT code 96372 (the original crosswalk code). In the CY 2021 PFS final rule, we did not finalize the proposed policy, and instead finalized a policy to maintain the CY 2019 payment amount for G0008, G0009 and G0010 (85 FR 84628). In the final rule, we also noted that we continued to seek additional information that specifically identifies the resource costs and inputs that should be considered to establish payment for vaccine administration services on a long-term basis.

As noted above, section 3713 of the CARES Act added the COVID–19 vaccine and its administration to the preventive vaccines covered under Medicare Part B under section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. Section 3713 of the CARES Act allows us to implement the amendments made by that section through ''program instruction or otherwise.'' In the November 4th COVID–19 IFC (85 FR 71147) implementing section 3713 of the CARES Act, we indicated that we would establish specific coding and payment rates for the COVID–19 vaccine and vaccine administration through technical direction to Medicare Administrative Contractors (MACs) and information posted publicly on CMS' website.

In December 2020, we publicly posted the applicable CPT codes for the Pfizer-BioNTech and Moderna COVID–19 vaccines and initial Medicare payment rates for administration of these vaccines upon the FDA's authorization of these vaccines. We announced an initial Medicare payment rate for COVID–19 vaccine administration of $28.39 to administer single-dose vaccines. For a COVID–19 vaccine requiring a series of two or more doses—for example, for both the Pfizer-BioNTech and Moderna products—we announced a payment rate for administration of the initial dose(s) of $16.94, which was based on the Medicare payment rate for administering the other preventive vaccines under section 1861(s)(10) of the Act. We also announced a payment rate for administering the second dose of $28.39, which was based on the payment rate that was proposed, but not finalized, for administration of the other preventive vaccines under section 1861(s)(10) of the Act in the CY 2021 PFS proposed rule, discussed in more detail above.

On March 15, 2021, we announced an increase in the payment rate for administering a COVID–19 vaccine to $40 per dose, effective for doses administered on or after March 15, 2021, which means the payment rate is $40 to administer a single dose product, and $40 each to administer the first and second dose in a two-dose regime ($80 total).

TABLE 22: Established Payment Rates for COVID-19 Vaccine Administration Services

CPT Code	Procedure Name	National Payment Amount For Physicians on or After March 15, 2021	National Payment Amount for Physicians Before March 15, 2021
0001A	Pfizer-Biontech Covid-19 Vaccine Administration – First Dose	$40.00	$16.94
0002A	Pfizer-Biontech Covid-19 Vaccine Administration – Second Dose	$40.00	$28.39
0011A	Moderna Covid-19 Vaccine Administration – First Dose	$40.00	$16.94
0012A	Moderna Covid-19 Vaccine Administration – Second Dose	$40.00	$28.39
0031A	Janssen/J&J Covid-19 Vaccine Administration	$40.00	$28.39

As discussed above, payment rates for suppliers such as physicians, NPPs, and mass immunizers for administering the Part B covered preventive vaccines have generally been based on a direct crosswalk to CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). This crosswalk code is paid under the PFS, and Medicare's process to value codes under the PFS relies in part on recommended resource inputs provided by the AMA RUC and steps to translate those recommended inputs into national RVUs.

In 2020, the RUC resubmitted its 2009 valuation recommendation for vaccine administration services described by CPT codes, including CPT codes 90460 (*Administration of first vaccine or toxoid component through 18 years of age with counseling*), 90471 (*Administration of 1 vaccine*), and 90473 (*Administration of 1 nasal or oral vaccine*). The AMA RUC also recently provided valuation recommendations for the CPT codes that describe the service to administer the COVID–19 vaccines.

As noted earlier, we also assign a payment rate for administering preventive vaccines under the OPPS by assigning an ambulatory payment classification (APC) to each service based on clinical and resource cost similarity to other services assigned to the APC. Geometric mean costs, which are generally used in establishing the prospective OPPS payments for each APC, are calculated using historical claims and cost report information. In CY 2021, CMS assigned HCPCS codes G0008, G0009 and G0010 to APC 5691 (*level 1 drug administration*), which has a national payment rate of $40 for CY 2021.

Our practice of setting payment rates for preventive vaccine administration services described by HCPCS codes G0008, G0009 and G0010 for physicians, NPPs, and mass immunizers by using the PFS approach (for example, a crosswalk to an existing CPT code) means that costs incorporated into the rate primarily reflect costs of furnishing the service in a physician office setting. It also means that the payment rate can be affected by other aspects of the PFS rate-setting methodology, such as the allocation of indirect PE, and broader changes to PFS codes and rates, including the multi-year phase-in of significant reductions in RVUs discussed earlier. We note that we have not historically collected or used information from other providers and suppliers, including pharmacies which are commonly enrolled as mass immunizers to furnish vaccines and vaccine administration services, for purposes of establishing a rate for these codes.

We are requesting feedback from stakeholders that would support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act for physicians, NPPs, mass immunizers and certain other providers and suppliers. We are interested in detailed feedback on the following questions, which we believe would assist us in establishing payment rates for these services that could be appropriate for use on a long-term basis.

- What are the different types of providers and suppliers that furnish preventive vaccines, and have these types of providers/suppliers changed as a result of the PHE for COVID–19? (We note that our claims data reflect the type of Medicare enrollment for those billing for the vaccine administration, but we are particularly interested in understanding additional, specific characteristics of the providers and suppliers that may not be distinguishable under the more general Medicare enrollment data.) We are also interested in whether different providers and suppliers furnish different aspects of the vaccine administration for the same beneficiary.
- What are the differences in incurred costs of furnishing flu, pneumonia and HBV vaccines compared to furnishing COVID–19 vaccines? Are there differences in the costs (per dose or otherwise) of furnishing a one-dose vaccine product vs. a two-dose vaccine product? Also, are there differences in cost of administering preventive vaccines furnished under the Part D benefit, such as the shingles vaccines, compared to those furnished under Part B?
- What are the resource costs that physicians, NPPs, mass immunizers and certain other suppliers incur when furnishing vaccines safely and effectively? We are interested in specific information on costs related to staffing/labor, infrastructure, patient onboarding/enrollment, vaccine storage and handling, vaccine procurement and coordination, supplies, CDC and state reporting requirements, patient counseling about safety and efficacy, and other costs we may not have considered. We are also interested in specific resource costs per vaccine dose within each cost category, if that is available.
- What are the impacts of the PHE for COVID–19 on resource costs incurred by vaccination providers, and do stakeholders envision that these impacts will continue after the PHE has ended? Following the end of the PHE, do you expect that the same types of vaccination providers and suppliers will continue to administer vaccines, or do you envision that this will change (if so, how, and what would be the primary factors driving the change)?
- As described previously, Medicare has generally relied on the PFS methodology for setting payment rates for HCPCS codes G0008, G0009 and

G0010. How should Medicare assess costs associated with furnishing these preventive vaccines outside of the physician office setting, such as in pharmacies, mass immunization sites, mobile vaccine clinics or other locations? In addition, we understand that there could be administrative burden associated with the routine collection of cost data to support more accurate rate-setting for suppliers that are vaccinating patients. Are there other ways to update and validate costs for a broader range of entities using existing data?

• Payment rates for vaccine administration currently vary by setting. For HCPCS codes G0008, G0009 and G0010, the CY 2021 national average payment rate for physicians, practitioners and other suppliers is $16.94, which is geographically adjusted, while for hospital outpatient departments it is $40. However, for COVID–19 vaccine administration, Medicare now pays $40 per administration in all settings, unless the vaccine in administered under certain circumstances in the beneficiary's home or residence (as discussed in more detail below). Should Medicare continue to pay differently for non-COVID–19 preventive vaccines furnished in certain settings or under certain conditions? If not, what factors contribute to higher costs for administration of non-COVID–19 vaccines that are not currently reflected in the Medicare payment rates?

• Should CMS use a different process to update the payment rates for administration of the preventive vaccines described in section 1861(s)(10) of the Act on an annual basis?

• In the last few years we have also crosswalked vaccine administration CPT codes 90460 (*Administration of first vaccine or toxoid component through 18 years of age with counseling*), 90461 (*Administration of vaccine or toxoid component through 18 years of age with counseling*), 90471 (*Administration of 1 vaccine*), 90472 (*Administration of vaccine*), 90473 (*Administration of 1 nasal or oral vaccine*), and 90474 (*Administration of nasal or oral vaccine*) to the same rate used by G0008, G0009 and G0010. How should Medicare address payment rates for these CPT codes under the PFS?

• Are there major differences between what Medicare pays physicians, NPPs and mass immunizers for non-COVID–19 preventive vaccine administration and what commercial insurers pay? To the extent possible we are also interested in feedback on specific rates used by other insurers.

2. Payment for COVID–19 Vaccine Administration in the Home

Effective June 8, 2021, we announced a new add-on payment with a national rate of $35.50 when a COVID–19 vaccine is administered in the beneficiary's home.[38] Under this new policy, providers and suppliers that administer a COVID–19 vaccine in a beneficiary's home under certain circumstances can bill Medicare for one of the existing COVID–19 vaccine administration CPT codes (0001A, 0002A, 0011A, 0012A, 0031A) along with HCPCS code M0201 (*COVID–19 vaccine administration inside a patient's home; reported only once per individual home per date of service when only COVID–19 vaccine administration is performed at the patient's home*). Providers and suppliers administering a COVID–19 vaccine in the home will be paid a national average payment $75.50 dollars per dose ($40 for COVID–19 vaccine administration and $35.50 for the additional payment for administration in the home, and both payments are geographically adjusted).

In establishing the additional payment for COVID–19 vaccine administration in the beneficiary's home, we also established certain conditions for the add-on payment described by HCPCS code M0201. More specifically, for purposes of this additional payment for administration of the COVID–19 vaccine in the beneficiary's home, we established that Medicare will make this payment when either of these situations applies:

• The patient has difficulty leaving the home to get the vaccine, which could mean any of these:

(1) They have a condition, due to an illness or injury, that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver;

(2) They have a condition that makes them more susceptible to contracting a pandemic disease like COVID–19; or

(3) They are generally unable to leave the home, and if they do leave home, it requires a considerable and taxing effort;

• The patient is hard-to-reach because they have a disability or face clinical, socioeconomic, or geographical barriers to getting a COVID–19 vaccine in settings other than their home. These patients face challenges that significantly reduce their ability to get vaccinated outside the home, such as challenges with transportation, communication, or caregiving.

We also specified that payment is made for HCPCS code M0201 if the sole purpose of the visit is to administer the COVID–19 vaccine. However, Medicare will not pay the additional amount if the provider or supplier furnished another Medicare covered service in the same home on the same date.

For purposes of this add-on payment for in-home COVID–19 vaccine administration, we announced that a home can be a private residence temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter), an apartment in an apartment complex or a unit in an assisted living facility or group home, or a patient's home that is made provider-based to a hospital during the PHE for COVID–19. As such, a home may be a domiciliary or rest home, meaning a facility, which provides room, board, and other personal assistance services (for example, an assisted living facility).

We also announced that the following locations are not considered to be the patient's home for purposes of the add-on payment for COVID–19 vaccine administration: Communal spaces of a multi-unit living arrangement; hospitals; Medicare SNFs, and Medicaid NFs, regardless of whether they are the patient's permanent residence; assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program. We are clarifying that an institution is not considered to be a patient's home if the institution meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, which includes hospitals and skilled nursing facilities, as well as most nursing facilities under Medicaid.[39]

Additionally, we established that assisted living facilities participating in the CDC Pharmacy Partnership for Long-Term Care Program partnership would not be eligible for this higher payment for COVID–19 vaccine administration in the home when their residents were vaccinated through this program.

In addition, the COVID–19 vaccine administration service must be furnished inside an individual's home. An individual unit in a multi-dwelling building is considered a home. For example, an individual apartment in an apartment complex or an individual bedroom inside an assisted living facility or group home is considered a home. We established that communal spaces of, or related to, congregate living arrangements (such as a communal area of an apartment or condominium complex, assisted living facility, group

[38] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

[39] 42 CFR 409.42(a).

home) are not considered a home for purposes of this add-on payment because multiple people could be vaccinated and monitored either simultaneously or in tandem in such communal spaces.

As noted in the code descriptor for HCPCS code M0201, this code can be billed only once per individual home per date of service. In situations where more than one Medicare beneficiary lives in the same individual home, the additional payment for COVID–19 vaccine administration in the home is limited to one time in that home on that day, while any additional COVID–19 vaccine administration services for other individuals in that same home would be paid at the generally applicable rate of approximately $40 without the additional in-home add-on payment amount.

We established the payment amount for HCPCS code M0201 for in-home vaccination to reflect the additional costs associated with administering the vaccine in the home, such as upfront administration costs like scheduling, the additional clinical time needed for post administration monitoring of a single patient, and public health reporting requirements. To identify an appropriate payment rate for HCPCS code M0201, we used the home health low utilization payment adjustment add-on factor for skilled nursing as a proxy for the increased resource costs, above those reflected in the base payment rate for COVID–19 vaccine administration, involved in arranging and furnishing COVID–19 vaccine administration services in the home. For home health services, we make a low utilization payment adjustment (LUPA) when, during a 30-day period of home health care (or prior to January 1, 2020, a 60-day episode of home health care) a patient receives minimal services (less visits than a predetermined threshold) and the home health agency is paid per visit rather than the full 30-day (previously 60-day) bundled payment amount (see 42 CFR 484.230). As stated in the CY 2008 HH PPS proposed rule, after the HH PPS went into effect we received comments and correspondence stating that the LUPA per-visit payment rates do not adequately account for the front-loading of costs in an episode. Commenters suggested that because of the small number of visits in a LUPA episode, HHAs have little opportunity to spread the costs of lengthy initial visits over a full episode (72 FR 25424). As such, under the Medicare home health payment system, LUPA add-on payments are made to account for the upfront fixed costs and prolonged visit lengths in a LUPA period/episode compared to those for non-LUPA periods/episodes. We believe the LUPA add-on factor for skilled nursing is an appropriate proxy for the upfront fixed costs and prolonged visit lengths that exemplify and constitute the increased resource costs involved in arranging and furnishing COVID–19 vaccine administration services in the home.

The CY 2021 LUPA add-on factor for skilled nursing is 1.8451, and we applied this to the base rate for COVID–19 vaccine administration of $40 per dose (effective March 15, 2021). This calculation results in a total proxy payment rate for in-home COVID–19 vaccine administration of approximately $74. Subtracting the $40 base rate for COVID–19 vaccine administration, which applies across most other settings, results in an additional proxy payment rate of roughly $34. To expedite access to this service and ensure consistency in payment rates for HCPCS code M0201 between health care professionals, other suppliers, and institutional providers, we established a payment rate that corresponds to the proxy we calculated based on the LUPA add-on factor using a reference to another proxy payment rate under the hospital OPPS. Specifically, we looked to APC payment amounts under the hospital OPPS that were similar to the $34 proxy amount and could be implemented with speed under the COVID–19 vaccine benefit (which relies on both institutional and professional claims processing systems). We identified New Technology APC 1494 under the hospital OPPS with a national payment rate of $35.50 as an appropriate reference payment amount for this service for most providers and suppliers, and established that amount as the national payment rate for HCPCS code M0201. That is, the national payment rate for HCPCS code M0201 is $35.50 for all providers and suppliers not paid reasonable cost.

In announcing the add-on payment for in-home COVID–19 vaccine administration, we noted that we established these policies on a ''preliminary basis to ensure access to COVID–19 vaccines during the public health emergency'' and that ''we continue to evaluate the needs of Medicare patients and these policies, and will address them in the future, as needed''.[40] We are using this proposed rule as a way to collect feedback on these policies and potential future changes.

- We are interested in feedback on our requirements, including the definition of the ''home'' and the types of clinical and non-clinical circumstances that make it difficult for a beneficiary to receive a COVID–19 vaccine outside the home. Do these requirements strike the appropriate balance of ensuring access to vaccines for vulnerable beneficiaries while also protecting against potential fraud? Should we maintain these requirements during the PHE as-is, and if not, what changes should we consider? Outside of the circumstances of the PHE that create a need for beneficiaries to be vaccinated as quickly and broadly as possible, under what circumstances do health care providers, suppliers, or others find particular need to vaccinate people at home rather than periodically in association with routine in-person visits?
- As noted, we established an add-on payment of $35.50, which is based on applying the LUPA add-on factor for skilled nursing to the national $40 payment rate for the base service as a proxy to reflect the additional resources involved in furnishing services in the home setting. We are interested in detailed feedback on the costs associated with furnishing COVID–19 vaccines in the home, and how these costs differ from costs of furnishing vaccines in traditional locations, such as a physician's office or mass immunization site.
- What other steps should we take related to program integrity and beneficiary protection with this new add-on payment for administering the COVID–19 vaccine in the home? What documentation should providers and suppliers that furnish vaccines in the home be required to maintain and/or provide?

We note that this add-on payment of $35.50 only applies when providers or suppliers furnish the COVID–19 vaccine in the beneficiary's home, and is not billable when providers and suppliers furnish a different preventive vaccine (influenza, pneumonia, HBV) in the home. We believe the additional payment is only appropriate for COVID–19 vaccines due to the unique circumstances of the PHE, as well as the upfront fixed costs and prolonged visit lengths that exemplify and constitute the increased resource costs involved in arranging and furnishing COVID–19 vaccine administration services in the home. However, we are interested in feedback on whether the same barriers that could prevent a beneficiary from obtaining a COVID–19 vaccine would also prevent them from obtaining other preventive vaccines, whether Medicare should make a similar add-on vaccine administration payment in those

[40] *https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment.*

circumstances, and whether the costs to furnish other preventive vaccines in the beneficiary's home would be consistent with the costs to furnish the COVID–19 vaccine.

3. Monoclonal Antibodies Used To Treat COVID–19

On November 10, 2020, the FDA issued an Emergency Use Authorization (EUA) for bamlanivimab monotherapy.[41] On November 21, 2020 the FDA issued an EUA for casirivimab and imdevimab, which are administered together.[42] On February 9, 2021, the FDA issued an EUA for bamlanivimab and etesevimab, which are also administered together.[43] On April 16, 2021, the FDA revoked the EUA for bamlanivimab monotherapy.[44] On May 26, 2021, the FDA issued an EUA for sotrovimab monotherapy.[45] On June 3, 2021, the FDA revised the EUA for casirivimab and imdevimab, which revised the dosing regimen from 2400mg (1200 mg of casirivimab and 1200 mg of imdevimab) to 1200mg (600 mg of casirivimab and 600 mg of imdevimab), authorized the addition of a new presentation consisting of a single vial of casirivimab and imdevimab co-formulated in a 1:1 ratio, and also authorized casirivimab and imdevimab to be administered together via subcutaneous injection in certain limited circumstances.[46] On June 24, 2021, the FDA issued an EUA for tocilizumab monotherapy.[47] Under the EUAs, for all of these products except for tocilizumab, they can be used for certain high-risk patients with mild-to-moderate COVID–19 with the goal of preventing further deterioration and hospitalization. Tocilizumab is authorized for hospitalized patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

When these products were authorized during the PHE for COVID–19, we made the determination to cover and pay for them under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. When we announced this approach, we also indicated that we would address ''potential refinements to payment for administering monoclonal antibody products to treat COVID–19 through future notice-and-comment rulemaking''.[48]

We make a separate payment for the products (when not given to the provider or supplier for free by the government) and for the service to administer them. We note that as of June 30, 2021, the monoclonal antibody products authorized by the FDA under an EUA include two products involving drugs administered together, casirivimab and imdevimab and bamlanivimab and etesevimab, the sotrovimab monotherapy, and the tocilizumab monotherapy. All four products may be administered through intravenous (IV) infusion, and casirivimab and imdevimab may be administered via subcutanoues injection in certain limited circumstances under the updated June 3rd EUA.

Initially, we established a national payment rate of $309.10 for the service to administer (through IV infusion only at the time) these products, which was based on one hour of infusion and post-infusion monitoring in the hospital outpatient setting. We note that while these products are typically infused over a period of roughly one hour, the EUA for casirivimab and imdevimab allows the product to be infused over a shorter time-period, such as 20 minutes, when appropriate. We note that, as of June 15, 2021, the EUAs require at least one hour of post infusion monitoring for all of the products available. On May 6, 2021, we increased the payment rate for administration to $450.00 and established a separate payment rate of $750.00 when a monoclonal antibody product used to treat COVID–19 is administered in a home or residence.[49]

The decision to cover and pay for monoclonal antibody products used to treat COVID–19 under the COVID–19 vaccine benefit prioritized access to these products during the COVID–19 pandemic by allowing almost all Medicare enrolled providers and suppliers, as permitted by state law and consistent with the terms of the EUA, to furnish and bill for administering these products across settings of care. Covering and paying for these services under the COVID–19 vaccine benefit also means that beneficiaries are not responsible for any cost sharing for the product or the service to administer it.

We note that Medicare considers other monoclonal antibody products—that is, monoclonal antibody products used in the treatment of other health conditions—''biologicals'' and pays for them based on the methodology in section 1847A of the Act when they are furnished in physician offices, ambulatory infusion clinics and under a similar methodology under the hospital OPPS. We also note that, for these care settings, we typically rely on the applicable AMA CPT codes to describe and pay for drug administration services performed by providers and suppliers.

As noted above, bamlanivimab monotherapy and casirivimab and imdevimab, administered together, were authorized in late 2020, we made the determination to cover and pay for them under the vaccine benefit in section 1861(s)(10) of the Act, and this decision prioritized beneficiary access for purposes of addressing the PHE for COVID–19. Since that time, the EUA for bamlanivimab monotherapy has been revoked, the EUA for casirivimab and imdevimab administered together has been revised to include a new presentation, a new dosing regimen, and a new route of administration (in certain limited circumstances), the sotrovimab monotherapy has been authorized and the tocilizumab monotherapy has been authorized. It is also becoming clear that, as more products enter the market, the federal government may not purchase them for distribution to providers and suppliers for free, as is the case with sotrovimab monotherapy and tocilizumab monotherapy. Given these fast-moving changes, we are seeking feedback on our approach to coverage and payment for COVID–19 monoclonal antibody products under the COVID–19 vaccine benefit. We are considering whether we should align payment and coverage for these products with our approach for other monoclonal antibody products following the end of the PHE. We believe that the context in which these products are furnished to beneficiaries after the end of the PHE may more closely resemble the circumstances under which similar drugs and biologics are ordinarily furnished, specifically to a more targeted patient population outside of a pandemic. Outside the context of the PHE, we believe treating these products like other drugs and biologics paid under section 1847A of the Act may better align Medicare coverage and payment policies for COVID–19 monoclonal antibody products with other monoclonal antibody products, which are purchased by providers and suppliers through

[41] *https://www.fda.gov/media/143602/download.*

[42] *https://www.fda.gov/media/143891/download.*

[43] *https://www.fda.gov/media/145801/download.*

[44] *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab.*

[45] *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19.*

[46] *https://www.regeneron.com/downloads/treatment-covid19-eua-fda-letter.pdf.*

[47] *https://www.fda.gov/media/150319/download.*

[48] *https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion.*

[49] *https://www.cms.gov/newsroom/press-releases/cms-increases-medicare-payment-covid-19-monoclonal-antibody-infusions.*

similar channels and administered using similar modalities. As noted above, coverage and payment for COVID–19 monoclonal antibodies under the COVID–19 vaccine benefit has meant that Medicare beneficiaries are not responsible for any cost-sharing, which is typically 20 percent of the allowed amount in most settings. We note that if Medicare were to pay for COVID–19 monoclonal antibody products under the methodologies in 1847A of the Act, it would mean that beneficiary co-insurance would apply, similar to how it applies to other drugs and biologics that are not paid for under a preventive vaccine benefit.

We also note that tocilizumab—typically sold under the brand name Actemra—was previously approved by the FDA for several indications.[50] As a result, during the PHE for COVID–19, Medicare has separate coding and payment rules for tocilizumab when it is furnished to patients with COVID–19 and in a manner consistent with the terms of the EUA, and for when tocilizumab is used for other clinical purposes. This may be confusing for hospital providers and we believe that treating these monoclonal antibody products like other drugs and biologics paid under section 1847A of the Act may help clarify these inconsistencies. We are interested in feedback on these issues.

We are also interested in additional feedback on the resource costs to administer COVID–19 monoclonal antibody products, such as costs associated with infrastructure, clinical labor, and equipment, including personal protective equipment. We recognize that administering monoclonal antibodies used to treat COVID–19 may be complex due the need to interact with beneficiaries that have active infections and manage the potential for spreading disease. We are interested in information on how the costs to furnish monoclonal antibodies used to treat COVID–19 compare with infusions of other complex biologics, and how the costs to furnish these products may be different when these products are administered in the home.

4. Summary

We have taken several steps to promote timely access to COVID–19 vaccines including monoclonal antibody products during the PHE for COVID–19. As explained above, we increased the payment rates we initially established for services to administer a COVID–19 injected vaccine and a COVID–19 infused or injected monoclonal antibody product. We also developed specific payment rates when these products are administered in the beneficiary's home. Taken together, these efforts signal our understanding of the importance of COVID–19 vaccines for the health of the individual beneficiary and the public. We also believe these efforts, and the PHE broadly, provide an opportunity to consider a more rational payment framework for the other preventive vaccines covered under Medicare Part B. We are encouraged by stakeholder engagement on these important issues and continue to seek information that reflects the resource costs that we should consider for vaccine administration services. We are interested in detailed feedback and verifiable data from the public to help inform whether we should consider making changes to payments for administering preventive vaccines, or develop separate payments for vaccine administration in the home.

We appreciate feedback from the public on these important issues regarding preventive vaccine administration, vaccine administration in the home, and monoclonal antibodies used to treat COVID–19.

K. Payment for Medical Nutrition Therapy Services and Related Services

Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) added section 1861(vv)(1) to the Act which provided Medicare coverage under Part B for Medical Nutrition Therapy (MNT) services when performed by registered dietitians and nutrition professionals pursuant to a referral from a physician.

Under section 1842(b)(18)(C) of the Act, registered dietitians and nutrition professionals are included in the list of NPPs that may bill Medicare and be paid directly for their services, effective January 1, 2002. To submit claims for MNT services, the registered dietitian or nutrition professional must enroll as such in accordance with our regulations at 42 CFR 414.64 and 424.510. Like other NPPs listed in section 1842(b)(18)(C) of the Act, registered dietitians and nutrition professionals who are employees or independent contractors of hospitals or physician groups may reassign their benefits to that hospital or physician group, as appropriate. The Medicare specialty code for ''dietitian/nutritionist'' is 71.

Under section 1833(a)(1)(T) of the Act, we were originally required to pay for MNT services at 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the PFS for the same services if the services had been furnished by a physician. We established payment regulations for MNT in our regulation at § 414.64 in the CY 2002 PFS final rule (66 FR 55278 through 55281 and 55332).

MNT services are defined as services that are furnished by a registered dietitian or nutrition professionals. These practitioners use three CPT® codes to bill for MNT assessment and intervention services with the referral of a physician. In cases where there is a second physician referral for MNT for the same patient within a calendar year (for example, based on a change in the patient's condition, diagnosis, or treatment regimen), the furnishing practitioner uses two other HCPCS codes to report these episodes. We have worked with stakeholders over the years to establish values for the services described by the five MNT codes.

The importance of MNT services for managing diabetes or renal disease, as well as the underutilization of the benefit by Medicare beneficiaries is discussed in this proposed rule at section III.H. More recently, stakeholders who are concerned about the low utilization rate for the services have requested that CMS make changes geared toward making MNT services more accessible to Medicare beneficiaries. These stakeholders believe the underutilization of MNT services is due to multiple factors. Some of these factors and our proposal to address them are discussed elsewhere in this rule (see section III.H.), including proposals to remove the requirement that the MNT referral be made by the ''treating physician'' and update the glomerular filtration rate (GFR) to reflect current medical practice. And, some factors are being considered here. First, stakeholders recommend that we modify the Medicare Claims Processing Manual (MCPM) to increase the visibility of MNT services by moving the provisions that address these services to appear near the provisions addressing other preventive services. (We note that MNT services are included in the definition of preventive services under section 1861(ddd)(3)(A) of the Act). Second, the stakeholders recommend that we revise our Medicare Benefit Policy Manual to address registered dietitians and nutrition professionals, and the MNT services they furnish, in a way that aligns with the provisions addressing other types of practitioners and the services they furnish.

[50] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125472s044lbl.pdf.*

We established the MNT regulations in the CY 2002 PFS final rule at § 410.130 through § 410.134 and § 414.64. There have since been two significant changes to payment for MNT services, which are discussed in more detail below: (1) We added MNT services to the Medicare telehealth services list and recognized that registered dietitians and nutrition professionals can furnish and bill for these services as distant site practitioners; and (2) section 4104 of the Affordable Care Act (ACA) amended the statute to remove application of the Medicare Part B deductible and coinsurance for MNT services effective January 1, 2011. In the CY 2006 PFS final rule (70 FR 70155 through 70157), we amended our regulation to add registered dietitians and nutrition professionals to the list of distant site practitioners for telehealth services at § 410.78(b)(2)(viii), and to add the three individual MNT services to the Medicare telehealth services list by adding ''individual medical nutrition therapy'' to § 414.65(a)(1). In the CY 2011 PFS final rule, we also added one of the group MNT codes (97804) to the Medicare telehealth services list (75 FR 73314 through 73315).

In the CY 2011 PFS final rule, (75 FR 73412 through 73430), we implemented the amendments made by section 4104 of the ACA, which were designed to remove financial barriers that may have prevented beneficiaries from obtaining certain preventive services. Section 4104 of the ACA amended section 1833(a)(1) of the Act by adding a new subparagraph (Y), which provides for Medicare Part B payment at 100 percent for preventive services described in section 1861(ddd)(3)(A) of the Act that are recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF); and, amended section 1833(b)(1) of the Act to specify that the annual Medicare Part B deductible does not apply to preventive services with a recommended grade of A or B by the USPSTF. Section 1861(ddd)(3) of the Act defines ''preventive services'' and includes MNT services as a preventive service through a cross references section 1861(ww)(2) of the Act. Additionally, section 4104 of the ACA amended section 1833(a)(1)(T) of the Act to specify that Medicare Part B payment is made at 100 percent (instead of 80 percent) of the lesser of the actual charge or 85 percent of the PFS payment amount for these services if they are recommended with an A or B rating by the USPSTF, thereby removing beneficiary coinsurance for these services. In the CY 2011 PFS final rule, we listed all preventive services and their recommended ratings from the USPSTF in Table 66 (66 FR 73420 through 73430), noting that all 5 MNT services received a grade of B from the USPSTF; and the last column in the table noted that the coinsurance and deductible are not applicable to these services beginning January 1, 2011. We codified the coinsurance exception for MNT services at § 410.152(l)(7) to indicate that Medicare Part B pays 100 percent of the Medicare payment amount, and the exception for the Medicare Part B deductible at § 410.160(b)(11).

At that time, the preventive services coinsurance and deductible changes were implemented through Change Request 7012 (Transmittal 864); however, we neglected to update the payment regulation for MNT services at § 414.64(a). As a result, we are now proposing to modify to the requirement at § 414.64(a) for payment of MNT services to reflect that MNT services, with their USPSTF recommended B rating, are paid at 100 percent of the lesser of the actual charges or 85 percent of the PFS amount.

Because the registered dietitian and nutrition professional are the only practitioners listed at section 1842(b)(18)(C) of the Act without a specific regulatory provision addressing them as a type of practitioner and specifying payment policies for their services, we are proposing to create a new section at § 410.72 to reflect these policies. We are proposing to include in the regulation at § 410.72 a cross reference to the regulation at § 410.134 that addresses the qualifications for registered dietitians and nutrition professionals. For covered services described at § 410.72(b), we are proposing as a condition of coverage to refer to medical nutrition therapy services as defined at § 410.130, and also to refer to the conditions for coverage of MNT services at § 410.132(a). Section 410.132(a) requires a referral for MNT services from a physician (an M.D. or D.O.), and that MNT services are personally performed by the registered dietitian or nutrition professional in a face-to-face encounter except when those services are furnished as a telehealth service as provided in § 410.78 of our regulations.

Because registered dietitians and nutrition professionals are also the primary specialty that furnishes diabetes self-management training (DSMT) services, we are proposing to include DSMT at § 410.72(b)(2) as an ''other service'' that registered dietitians and nutrition professionals can provide in cases where the registered dietitian or nutrition professional is a certified provider of DSMT services as specified at section 1861(qq)(2)(A) of the Act; and they have submitted necessary documentation to, and are accredited by, a CMS-approved accreditation organization, as specified in § 410.141(e) for DSMT services. We also propose to address in the regulation at § 410.72(b)(2) the current requirement that, as specified in the regulation at § 410.141(b)(1), DSMT services require a referral from the physician or qualified NPP (as defined in § 410.32(a)(2)) who is treating the beneficiary's diabetes condition. We also propose to specify in the regulation at § 410.72(b)(3) that MNT and DSMT services cannot be furnished together on the same date of service as detailed in the national coverage determination for MNT services (see *https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=252*); and, that neither MNT nor DSMT services can be furnished incident to the professional services of a physician or other practitioner. For MNT services, we are proposing to clarify that MNT services cannot be provided incident to the services of a billing physician. As a distinct, stand-alone benefit under Medicare Part B at section 1861(s)(2)(V) of the Act, MNT services cannot be furnished incident to a physician's professional service that is separately specified at section 1861(s)(2)(A) of the Act. Further, if a physician also meets the qualifications to bill Medicare as a registered dietitian or nutrition professional (although not necessarily enrolled as one), they would have to personally provide any MNT services as explained above, meaning that those services could not be furnished by auxiliary personnel incident to their own professional services. For DSMT services, we are also proposing to clarify that DSMT services cannot be provided incident to the services of a billing physician or practitioner. DSMT is a distinct benefit under Medicare Part B, as specified in a stand-alone statutory provision at section 1861(s)(2)(S) of the Act. Approved DSMT entities are separately recognized programs, rather than individuals or practitioners, that provide DSMT services in accordance with their accreditation from a CMS-approved organization under § 410.142, indicating that the entity meets a set of quality standards described in § 410.144. Even when the DSMT services are billed by a physician or other practitioner, such as the DSMT certified provider, the physician or other practitioner could not provide

DSMT services directly, unless they themselves are also an approved DSMT entity. If a physician or practitioner is an approved entity, the DSMT services must be provided in accordance with the requirements to furnish such services. For these reasons, we are adding at § 410.72(b)(3)(ii) that neither MNT nor DSMT may be furnished and billed incident to the professional services of a physician or practitioner, where applicable.

As such, we are proposing to add at 410.72(d) that the registered dietitian or nutrition professional can be paid for their professional services only if those services have been personally performed by them. Section 1861(vv) of the Act clearly indicates that MNT services are only provided by registered dietitians and nutrition professionals; and this was reiterated at § 410.134 in the CY 2002 PFS final rule (66 FR 55331). In addition, in the CY 2002 PFS final rule, we established a regulation at § 410.132(a) that requires registered dietitians and nutrition professionals to provide MNT services and that those services consist of face-to-face nutritional assessments and interventions in accordance with nationally accepted dietary or nutritional protocols. Both of these provisions were codified in our regulations at §§ 410.132(a) and 410.134.

In the CY 2001 PFS final rule, we discussed that registered dietitians and nutrition professionals who are enrolled in Medicare could furnish services in various settings including private practices and outpatient hospitals, but that payment for MNT services would not be made when beneficiaries are inpatients in Part A stays in hospitals and skilled nursing facilities (SNFs) (66 FR 55279). We explained that our payment to hospitals and SNFs includes payment for MNT services. We established these regulations at § 414.64(c). We are proposing to add these rules to our regulation at § 410.72(c)(1) and (2), as on payment for services of registered dietitians and nutrition professionals when beneficiaries are inpatients of hospitals and SNFs. Also, in the CY 2001 PFS final rule, we finalized, in accordance with section 1861(s)(2)(V)(ii) of the Act, that there is no coverage for MNT services available for beneficiaries who are receiving maintenance dialysis for which payment is made under section 1881 of the Act, that is, services from an end-stage renal disease (ESRD) facility. This was codified at § 410.132(b). We are proposing to add this non-covered service to our regulation at § 410.72(c)(3) and note its cross reference to § 410.132(b).

In accordance with section 1842(b)(18)(B) of the Act, the registered dietitian or nutrition professional must accept assignment, meaning that they must accept the payment amount Medicare approves as payment in full and collect nothing from the beneficiaries for those services for which Medicare pays 100 percent of the Medicare approved amount or only collect the difference between the Medicare approved amount and the Medicare Part B payment in accordance with § 424.55. We are proposing to add at § 410.72(f) that the services of a registered dietitian or nutrition professional are provided on an assignment-related basis. Because Medicare pays 100 percent of the Medicare approved amount for MNT covered services, this means that beneficiaries cannot be billed any amount for MNT covered services. For other services, including DSMT, for which the Medicare Part B coinsurance percentage is 20 percent, a registered dietitian or nutrition professional must not collect amounts in excess of the limits specified in § 424.55 of our regulation, and if they do, they must refund the full amount of the impermissible charge to the beneficiary. Finally, we note that the proposed regulatory text for § 410.72(f) is consistent with the text in existing §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2). We are also considering whether alternate regulatory text that cross-refers to the assignment requirements in § 424.55 would provide additional clarity. Specifically, we are considering whether to specify restrictions at § 410.72(f) to specify that the services of a registered dietitian or nutrition professional are provided on an assignment-related basis, and the registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. In addition, if a beneficiary has made payment for a service in excess of these limits, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary.

To ensure maximum consistency in our regulations, if we finalize the alternate regulatory text for § 410.72(f), we would also make corresponding revisions to §§ 410.74(d)(2), 410.75(e)(2), 410.76(e)(2) and 410.77(d)(2). We seek public comments on the clearest language to describe the assignment requirements.

We are seeking comment on our proposals.

III. Other Provisions of the Proposed Rule

A. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

As discussed in 42 CFR part 405, subpart X, RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PA), certified nurse midwives (CNMs), clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home health agencies. A Transitional Care Management (TCM) service can also be an RHC or FQHC visit. In addition, a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT program may also be considered an FQHC visit. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount. As of April 1, 2021, all RHCs are subject to a payment limit for the AIR, and this limit will be determined for each RHC in accordance with section 130 of the Consolidated Appropriations Act, 2021, described below.

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable

Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care.

2. Payment Methodology for RHCs

a. Background

As we discussed previously, under Medicare Part B, payment to RHCs for services (defined in § 405.2411) furnished to beneficiaries is made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit (discussed in section III.A.3. of this proposed rule) and annual reconciliation. Our regulations, at § 405.2470 provides that RHCs are required to submit cost reports to allow the Medicare Administrative Contractor (MAC) to determine payment in accordance with 42 CFR part 405, subpart X, and instructions issued by CMS. The statutory payment requirements for RHC services are set forth at section 1833(a)(3) of the Act, (as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [51]), which states that RHCs are paid reasonable costs ''* * * less the amount a provider may charge as described in clause of section 1866(a)(2)(A), but in no case may the payment exceed 80 percent of such costs. The beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

We explain in § 405.2464(a) the AIR is determined by the MAC at the beginning of the cost reporting period. The MAC calculates the AIR that will apply for the upcoming cost reporting period for each RHC by dividing the estimated total allowable costs by estimated total visits for RHC services. The MAC also periodically reviews the AIR throughout the cost reporting period to assure that payments approximate actual allowable costs and visits and may adjust the rate. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services (§ 405.2468).

Medicare payment for RHC services are ultimately determined at cost report settlement. That is, during the annual reconciliation as explained in § 405.2466, MACs determine the total reimbursement amount due the RHC for covered services furnished to Medicare beneficiaries based on the reporting period. The total reimbursement amount due is compared with total payments made to the RHC for the reporting period, and the difference constitutes the amount of the reconciliation. If the total reimbursement due the RHC exceeds the payments made for the reporting period, the MAC makes a lump-sum payment to the RHC to bring total payments into agreement with total reimbursement due the RHC. If the total payments made to an RHC for the reporting period exceed the total reimbursement due the RHC for the period, the MAC arranges with the RHC for repayment.

In the event a new RHC is in its initial reporting period, and the MAC does not have a cost report to set its AIR, the RHC provides the MAC an estimate of what it expects its costs to be for its initial reporting period. In the Provider Reimbursement Manual (Pub. 15–2), chapter 46, section 4600,[52] we explain that for an RHC's initial reporting period, the clinic completes the cost report's worksheets with estimates of costs and visits and other information required by the reports. The MAC uses these estimates to determine an interim rate of payment for the RHC. This interim rate may be adjusted throughout the reporting period. Following the end of the RHC's reporting period, the RHC is required to submit its worksheets, using data based on its actual experience for the reporting period. The AIR for the following year will then be based on the RHC's actual experience.

As discussed in Pub. 100–02, Chapter 13, section 80.2,[53] when RHCs are part of the same organization with more than one RHC, they may elect to file consolidated cost reports rather than individual cost reports. Under this type of reporting, each RHC in the organization need not file individual cost reports. Rather, the group of RHCs may file a single report that accumulates the costs and visits for all RHCs in the organization. In order to qualify for consolidation reporting, all RHCs in the group must be owned, leased, or through any other agreement, controlled by one organization.

3. RHC Payment Limit Per-Visit

a. Background

Prior to the Balanced Budget Act of 1997 [54] (BBA), the payment methodology for an RHC depended on whether it was ''provider-based'' or ''independent.'' Specifically, payment to provider-based RHCs for services furnished to Medicare beneficiaries was made on a reasonable cost basis by the provider's MAC in accordance with the regulations at 42 CFR part 413; whereas payment to independent RHCs for services furnished to Medicare beneficiaries was made on the basis of a uniform all-inclusive rate payment methodology in accordance with 42 CFR part 405, subpart X. In addition, payment to independent RHCs also was subject to a maximum payment per visit (also referred to as a ''payment limit per-visit'', ''upper payment limit per-visit'', or ''cap'') as set forth in section 1833(f) of the Act. This national statutory payment limit was set at $46 and was adjusted annually based on the Medicare Economic Index (MEI) described in section 1842(b)(3) of the Act.

Section 1833(f) of the Act was further amended by section 4205(a) of the BBA) (Pub. L. 105–33) to permit an exception to the national statutory payment limit for RHCs based in rural hospitals with less than 50 beds. Our guidance directed Medicare intermediaries to use the bed definition at § 412.105(b) and the rural definition at § 412.62(f)(1) to determine which RHCs are eligible for the exception. The hospital bed definition was based on available bed days and the rural definition was based on the Office of Management and Budget's

[51] *https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf.*

[52] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935.*

[53] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf.*

[54] *https://www.congress.gov/105/plaws/publ33/PLAW-105publ33.pdf.*

metropolitan statistical area (MSA) method.

Section 224 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F of Consolidated Appropriations Act of 2001) (BIPA) [55] (Pub. L. 106–554, December 21, 2000) further amended section 1833(f) of the Act by expanding the eligibility criteria for receiving an exception to the national statutory payment limit for RHCs. Specifically, this section of BIPA extended the exemption to RHCs based in small, urban hospitals. Effective July 1, 2001, all hospitals of less than 50 beds were eligible to receive an exception from the per visit payment limit for their RHCs.

As discussed in Change Request 1958, Transmittal A–01–138 issued on December 6, 2001, following the implementation of the BBA provision, CMS announced an alternative bed size definition for very rural, sole community hospitals with seasonal fluctuations in patient census. The MAC reviews the number of beds twice a year to determine whether the provider-based RHC meets the exception, during the Desk Review process and during the interim rate process (that is, determining the RHC's AIR). The provider-based RHC continues to receive the exception until the hospital which they are affiliated with submits a cost report with more than 50 beds. However, in the May 8, 2020 **Federal Register**, in response to the PHE for COVID–19, we published the ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' interim final rule with comment period (85 FR 27550) (May 8, 2020 IFC). In the May 8, 2020 IFC, we implemented, on an interim basis, a change to the period of time used to determine the number of beds in a hospital at § 412.105(b) for purposes of determining which provider-based RHCs are subject to the payment limit (85 FR 27569). That is, for the duration of the PHE, we adopted an interim final policy to use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for application of this policy. As such, RHCs with provider-based status that were exempt from the national statutory payment limit in the period prior to the effective date of the PHE (January 27, 2020) would continue to be exempt from the bed count requirement for the duration of the PHE for the COVID–19 pandemic, as defined at § 400.200, even if the hospital raised its bed count above 50. Once the PHE for COVID–19 ends, hospitals need to lower their bed count to less than 50 beds to utilize an RHC policy that has such a requirement.

[55] *https://www.congress.gov/106/plaws/publ554/PLAW-106publ554.pdf.*

b. Section 130 of the Consolidated Appropriations Act, 2021

Section 130 of the Consolidated Appropriations Act, 2021 (CAA 2021) (Pub. L. 116–260, December 27, 2020) updated section 1833(f) of the Act by restructuring the payment limits for RHCs beginning April 1, 2021. We note that section 2 of H.R. 1868 (Pub. L. 117–7), enacted April 14, 2021, provided a technical correction to section 1833(f) of the Act. The amendments made by this technical correction take effect as if included in the enactment of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260).

Section 1833(f)(2) of the Act, as added by section 130 of the CAA 2021, states that beginning April 1, 2021, RHCs will begin to receive an increase in their payment limit per visit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Then, in a subsequent year, at the limit established for the previous year increased by the percentage increase in the MEI applicable to primary care services furnished as of the first of such subsequent year. This provision also subjects all new RHCs (including provider-based RHCs in a hospital with less than 50 beds and enrolled in Medicare after December 31, 2020) to the national statutory payment limit.

The national statutory payment limit for RHCs over an 8-year period is as follows:

- In 2021, after March 31, at $100 per visit;
- In 2022, at $113 per visit;
- In 2023, at $126 per visit;
- In 2024, at $139 per visit;
- In 2025, at $152 per visit;
- In 2026, at $165 per visit;
- In 2027, at $178 per visit; and
- In 2028, at $190 per visit.

Beginning April 1, 2021, provider-based RHCs that meet the qualifications in section 1833(f)(3)(B) of the Act, as added by section 130 of the CAA 2021 and amended by Public Law 117–7, are entitled to special payment rules, as described in section 1833(f)(3)(B) of the Act. That is, a provider-based RHC must meet the following criteria to have its payment limit established based on its per visit payment amount (or AIR):

- As of December 31, 2020, was in a hospital with less than 50 beds and after December 31, 2020 in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the PHE for COVID–19); and one of the following circumstances:

++ As of December 31, 2020, was enrolled in Medicare (including temporary enrollment during the PHE for COVID–19); or

++ Submitted an application for enrollment in Medicare (or a request for temporary enrollment during the PHE for COVID–19) that was received not later than December 31, 2020.

Specifically, beginning April 1, 2021, for provider-based RHCs that had a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be set at an amount equal to the greater of: (1) The per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; *or* (2) the national statutory payment limit for RHCs per visit. The details of the most recent MEI rebasing and revising is discussed in the CY 2011 PFS final rule with comment period (75 FR 73262). The MEI increase for an update year is based on historical data through the second quarter of the prior calendar year. For example, the 2021 update reflects data through the second quarter 2020. We note that the MEI percentage increase for CY 2021 is 1.4 percent, which reflects historical MEI data through the 2nd quarter 2020 and historical multifactor productivity (MFP) data through 2019. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the MEI and other CMS market baskets, *https://ihsmarkit.com/index.html*.

In a subsequent year (that is, after 2021), the provider-based RHC's payment limit per visit shall be set at an amount equal to the *greater of:* (1) The payment limit per visit established for the previous year, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of such subsequent year; *or* (2) the national statutory payment limit for RHCs. The proposed CY 2022 MEI update is 1.8 percent based on the IGI 1st quarter 2021 forecast of the MEI and productivity adjustment, which reflects historical MEI data through 4th quarter 2020 and historical MFP data through 2019. As is our general practice, we are

proposing that if more recent data become available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the MEI percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the final CY 2022 MEI update.

For provider-based RHCs that meet certain requirements, but did not have a per visit payment amount (or AIR) established for services furnished in 2020, the payment limit per visit shall be at an amount equal to the greater of: (1) The per visit payment amount applicable to the provider-based RHC for services furnished in 2021; *or* (2) the national statutory payment limit for RHCs.

In a subsequent year (that is, after 2022), the provider-based RHCs payment limit per visit will be the *greater of:* (1) The payment limit per visit established for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year; *or* (2) the national statutory payment limit for RHCs.

A provider-based RHC that meets the qualifications of section 1833(f)(3)(B) of the Act, as corrected by Public Law 117–7 will lose this designation if the hospital does not continue to have less than 50 beds, beyond the exemptions provided for the PHE for COVID–19. If this occurs, the provider-based RHC will be subject to the statutory payment limit per visit applicable for such year and not able to regain the specified provider-based payment limit.

Provider-based RHCs that are newly enrolled beginning January 1, 2021, and after are subject to the national statutory payment limit applicable for such year for RHCs.

c. Implementation of Section 130 of the Consolidated Appropriations Act, 2021

As we stated above, RHCs began to receive an increase in the national statutory payment limit over an 8-year period, with a prescribed amount for each year from 2021 through 2028. Prior to this legislation, the CY 2020 national statutory payment limit for RHCs was $86.31. Then for calendar year 2021, there are two sets of payment rules for RHCs. For the period before March 31, 2021, independent RHCs and provider-based RHCs that did not meet specified requirements were subject to the payment limit of $87.52 that CMS announced in Change Request 12035, Transmittal 10413 issued on October 29, 2020.[56] Provider-based RHCs that met specified requirements were not subject to a payment limit for the first quarter of calendar year 2021. However, beginning April 1, 2021, in accordance with section 130 of the CAA 2021, all RHCs are now subject to a payment limit. For example, beginning April 1, 2021 through December 31, 2021 the national statutory payment limit for RHCs is $100.00. To prepare for this change in payment limits during the calendar year, Change Request 12185, Transmittal 10679 was issued on March 16, 2021, to implement an increase in the RHC statutory payment limit per visit and establish the provider-based RHC payment limits per visit, which went in effect on April 1, 2021. We note, Change Request 12185, Transmittal 10679 was rescinded and replaced by Transmittal 10780 issued on May 4, 2021 to reflect the technical corrections in section 2 of H.R. 1868 (Pub. L. 117–7). We also note that this provision does not impact the way beneficiary coinsurance is calculated as described in § 405.2410(b)(1).

i. Specified Provider-Based RHCs

In section III.A.3.b. of this proposed rule, we discuss the qualifications specified in section 1833(f)(3)(B) of the Act, as amended by Public Law 117–7, that determine if a provider-based RHC is entitled to the special payment rules described in section 1833(f)(3)(A) of the Act. To determine if an RHC was in a hospital with less than 50 beds as of December 31, 2020, we will review each provider-based RHC using the existing bed count review process, as described above, to determine if this criterion is met. In addition, this process generally includes ongoing review by the MACs two times a year. The beds to be counted for purposes of this criterion are described in § 412.105(b), in accordance with existing policy.

In continuing with our existing policy and in accordance with section 1833(f)(3)(B)(i) of the Act which states that ''as of December 31, 2020, was in a hospital with less than 50 beds and after such date such hospital continues to have less than 50 beds'' an RHC will retain its specified provider-based status until the hospital which they are affiliated submits a cost report with more than 50 beds. An RHC will no longer retain its specified provider-based status nor be eligible for specified status in the future once the hospital which they are affiliated submits a cost report with more than 50 beds. However, in response to the PHE for COVID–19 and in accordance with section 1833(f)(3)(B)(I) of the Act, we will apply the policy that allows for increased hospital bed counts, as described in the May 8, 2020 IFC, for purposes of determining this bed count criterion for specified provider-based RHC status. That policy specifies that for the duration of the PHE, we will use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count. We note that the criteria specified in section 1833(f)(3)(B)(i) of the Act specifies ''in a hospital with less than 50 beds'' therefore, beginning April 1, 2021, we will apply the bed definition at § 412.105(b) exclusively.

Section 1833(f)(3)(B)(ii) of the Act, as added by section 2 of Public Law 117–7, requires that these specified provider-based RHCs as of December 31, 2020 are ''enrolled under 1866(j) (including temporary enrollment during such emergency period for such emergency period),'' or ''submitted an application for enrollment under section 1866(j) of the Act (or a request for such a temporary enrollment for such emergency period) that was received not later than December 31, 2020.'' We propose that the RHC's effective date of enrollment (as established under existing regulations) would be used in our determination as to whether an RHC is enrolled under section 1866(j) of the Act as of December 31, 2020. In addition, with regard to an application for enrollment under section 1866(j) of the Act or a request for temporary enrollment, we propose to use the date an application or request was received to determine if the RHC met the qualification. RHCs that established temporary locations for the purpose of responding to the PHE for COVID–19, in accordance with their state pandemic response plan, are permitted to enroll and receive temporary Medicare billing privileges. When the PHE for COVID–19 ends, an RHC that had been temporarily enrolled under the flexibilities described above must submit a complete CMS–855 enrollment application in order to establish full Medicare billing privileges. Failure to do so will result in the deactivation of the RHC's temporary billing privileges. No payments can be made for services provided while the temporary billing privileges are deactivated. For RHCs enrolled through the temporary enrollment process that will need to submit a complete CMS–855 enrollment application, we propose, regardless of when the temporarily enrolled RHC is fully enrolled, that the RHC would be entitled to the special payment rules as long as it was

[56] *https://www.cms.gov/files/document/r10413cp.pdf.*

temporarily enrolled as of December 31, 2020 or a temporary enrollment request was received by December 31, 2020, and it meets the bed count requirement.

As stated above, section 1833(f)(3)(A) of the Act instructs Medicare to set payment limits per visit for these specified provider-based RHCs under certain payment rules. Specifically, beginning April 1, 2021, a payment limit per visit shall be set at an amount equal to the *greater of:* (1) The per visit payment amount applicable to such RHC for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021; *or* (2) the statutory payment limit per visit as described in section 1833(f)(2) of the Act. For subsequent years, in accordance with section 1833(f)(3)(A)(ii) of the Act, that payment amount is increased by the percentage increase in the MEI or the statutory payment limit described in section 1833(f)(2) of the Act, whichever is greater.

We interpret the ''per visit payment amount'' to align with the interim rate process the MACs use in determining an RHC's AIR (discussed above in section III.A.2. of this proposed rule). That is, as explained in § 405.2464(a) the AIR is determined by the MAC using the most recently available cost report. Therefore, with regard to ''services furnished in 2020'' we interpret this to mean the period at which the services were furnished in 2020 and that costs for those services were reported. We understand that there may be more than one cost report that reports costs for services furnished in calendar year 2020. However, since section 130 of the CAA 2021 states that the ''per visit payment amount'' is to be increased by the CY 2021 MEI, if a provider has a cost reporting period that differs from a calendar year time-period then the MACs should use data based on the relevant cost report period ending in 2020.

Finally, we understand that certain RHCs file consolidated cost reports, as described above. For specified provider-based RHCs, existing RHCs that are independent, and existing RHCs that are in a hospital with greater than 50 beds, we will continue to use the parent RHCs' cost reports to determine the payment limit per visit (for multi-facility RHC systems), as consolidated cost reporting reduces the reporting burden and cost report preparation time for RHCs. Combining multiple individual RHC cost reports into a consolidated cost report allows RHCs to take advantage of administrative efficiencies and economies of scale that do not exist otherwise.

However, in accordance with section 1833(f)(2) of the Act, all new provider-based RHCs and independent RHCs enrolled, as of January 1, 2021, shall have a payment limit established at the national statutory payment limit for RHCs. Therefore, beginning with RHCs enrolled in Medicare as of January 1, 2021, we will no longer allow new RHCs to file consolidated cost reports.

ii. All Other RHCs

While there are criteria that allow for specified provider-based RHCs to be eligible for certain payment rules, all other RHCs are subject to payment limits as described in section 1833(f)(2) of the Act. While there may be new RHCs that are ''in a hospital with less than 50 beds'' and ''enrolled under section 1866(j)'', they will not have met these criteria by December 31, 2020. Thus, any new RHCs will also be subject to the national statutory payment limits as described in section 1833(f)(2) of the Act.

Though the payment limit is described, these RHCs will still have an AIR per visit determined based on their allowable costs for each year going forward. However, the payment limit that is established will be the maximum amount that an RHC will be paid by Medicare per visit. As discussed above, at the time of reconciliation, if an RHC's costs per visit are above the AIR, they will be paid an amount that reflects these additional costs, not to exceed the payment limit. If an RHC's costs per visit are below the AIR, then CMS will collect any overpayment for that visit. To implement this provision beginning April 1, 2021, CMS instructed the MACs to increase the payment limits to $100 per visit.

Although the payment limit per-visit as set forth in section 1833(f) of the Act has already been implemented in administrative instructions issued to the MACs in Change Request 12185, we are proposing revisions to § 405.2462 to reflect the provisions set forth in section 1833(f)(2) and (3) of the Act. We solicit comment on these revisions and on our proposals regarding the implementation of section 130 of the CAA 2021.

3. Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients

a. Background

In the Fiscal Year (FY) 2021 Hospice Payment Rate Update final rule (85 FR 47070) we explain that hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for relief of pain and for symptom management. Palliative care is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit. The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment.

A hospice uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, with the goal of making the beneficiary as physically and emotionally comfortable as possible. As referenced in our regulations at § 418.22(b)(1), to be eligible for Medicare hospice services, the patient's attending physician (if any) and the hospice medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3; that is, the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

Section 1861(dd)(3)(B) of the Act defines the term ''attending physician'' to mean, with respect to an individual, the physician, the NP or PA who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

As explained in Pub. 100–02, chapter 9, section 20.1,[57] the attending physician is a doctor of medicine or osteopathy who is legally authorized to practice medicine or surgery by the state in which he or she performs that function, an NP, or PA, and is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care. An NP is defined as a registered nurse who performs such services as legally authorized to perform (in the state in which the services are performed) in accordance with state law (or state regulatory mechanism provided by state law) and who meets training, education, and experience requirements described in § 410.75. A PA is defined as a professional who has graduated from an accredited PA educational program who

[57] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c09.pdf.*

performs such services as he or she is legally authorized to perform (in the state in which the services are performed) in accordance with state law (or state regulatory mechanism provided by state law) and who meets the training, education, and experience requirements as the Secretary may prescribe. The PA qualifications for eligibility for furnishing services under the Medicare program can be found in the regulations at § 410.74 (c).

RHCs and FQHCs are not authorized under the statute to serve in the role of an attending physician. However, a physician, NP, or PA who works for an RHC or FQHC may provide hospice attending physician services during a time when they are not working for the RHC or FQHC (unless prohibited by their RHC or FQHC contract or employment agreement). These services would not be considered RHC or FQHC services, since they are not being provided by an RHC or FQHC practitioner during RHC or FQHC hours. The physician, NP, or PA would bill for services under Part B using their own provider number/NPI. In addition, any service provided to a hospice beneficiary by an RHC or FQHC practitioner must comply with Medicare prohibitions on commingling. Further information regarding commingling is available in Pub. 100–02, Chapter 13, section 100.[58]

b. Section 132 of the Consolidated Appropriations Act 2021

Section 132 of the CAA 2021 amended section 1834(o) of the Act and added a new section 1834(y) to the Act, to provide the authority for both FQHCs and RHCs, respectively, to receive payment for hospice attending physician services. Specifically, when a designated attending physician employed by or working under contract with an FQHC or RHC furnishes hospice attending physician services (as described in section 1812(d)(2)(A)(ii) of the Act) on or after January 1, 2022, the FQHC or RHC is eligible to receive payment under the FQHC PPS or RHC AIR, respectively.

Therefore, beginning January 1, 2022, a physician, NP, or PA who is employed by or working under contract with an RHC or FQHC may provide hospice attending physician services during a time when they are working for the RHC or FQHC. The RHC or FQHC would bill for these services as they would for any other qualified service to be paid the RHC AIR or the FQHC PPS rate, respectively. When the RHC/FQHC furnishes a hospice attending physician service that has a technical component, the provider furnishing the technical component would go to the hospice for payment as discussed in the Medicare Claims Processing Manual at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c11.pdf*.

We propose to codify the new statutory provisions as described in section 132 of the CAA 2021 in 42 CFR 405, subpart X, specifically:

- At § 405.2411, Scope of benefits, we are amending § 405.2411(b) to reflect that hospice attending physician services are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, NP, or PA designated by the patient at the time of hospice election as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished.
- At § 405.2446, Scope of services, we are amending § 405.2446(c) to include that FQHC services are covered when they are hospice attending physician services furnished during a hospice election.

4. Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs

a. Background

In the CY 2013 PFS final rule (77 FR 68978 through 68994), Medicare payment for TCM services furnished by an RHC or FQHC practitioner was effective January 1, 2013, consistent with the effective date of payment for TCM services under the PFS. We adopted two CPT codes (99495 and 99496) to report physician or qualifying NPP care management services for a patient following a discharge from an inpatient hospital or SNF, an outpatient hospital stay for observation or partial hospitalization services, or partial hospitalization in a community mental health center. As a condition for receiving TCM payment, a face-to-face visit was required.

In the CY 2016 PFS final rule with comment period (80 FR 71080 through 71088), we finalized policies for payment of CCM services in RHCs and FQHCs. Payment for CCM services in RHCs and FQHCs was effective beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that would place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Payment was made for CCM services when CPT code 99490 was billed alone or with other payable services on an RHC or FQHC claim, and the rate was based on the PFS national average non-facility payment rate. The requirement that RHC or FQHC services be furnished face-to-face was waived for CCM services furnished to an RHC or FQHC patient because CCM describes non face-to-face services.

In the CY 2018 PFS final rule, (82 FR 53172 through 53180), we finalized payment for CCM, general Behavioral Health Integration (BHI), and the psychiatric collaborative care model (CoCM) services furnished by RHCs or FQHCs on or after January 1, 2018, described by HCPCS codes G0511 and G0512. HCPCS code G0511 is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month. HCPCS code G0512 is a psychiatric CoCM code for use by RHCs or FQHCs when at least 70 minutes of initial psychiatric CoCM services or 60 minutes of subsequent psychiatric CoCM services are furnished to a patient in a calendar month. The payment amount for HCPCS code G0511 is set at the average of the three national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS rates. The three codes are CPT code 99490 (*20 minutes or more of CCM services*), CPT code 99487 (*60 minutes or more of complex CCM services*), and CPT code 99484 (*20 minutes or more of BHI services*). The payment amount for HCPCS code G0512 is set at the average of the two national non-facility PFS payment rates for the CoCM codes and is updated annually based on the PFS rates. The two codes are CPT code 99492 (*70 minutes or more of initial psychiatric CoCM services*) and CPT code 99493 (*60 minutes or more of subsequent psychiatric CoCM services*).

In the CY 2019 PFS final rule (83 FR 59687), we finalized that effective January 1, 2019, the payment rate for HCPCS code G0511 (*General Care Management Services*) is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491.

In the CY 2020 PFS final rule with comment period (84 FR 62692), we added HCPCS code G2064 (*30 minutes of PCM services furnished by physicians or NPPs*) and G2065 (*30 minutes or more of PCM services furnished by*

[58] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c13.pdf*.

clinical staff under the direct supervision of a physician or NPP) as a general care management service and included it in the calculation of HCPCS code G0511. Beginning January 1, 2021, the payment for HCPCS code G0511 is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491, and HCPCS codes G2064 and G2065, and is updated annually based on the PFS rates. Additional information on CCM requirements is available on the CMS Care Management web page [59] and on the CMS RHC [60] and FQHC [61] web pages.

Currently, RHCs and FQHCs may not bill for TCM services for a beneficiary if another practitioner or facility has already billed for CCM services for the same beneficiary during the same time-period.

b. Concurrent Billing for Chronic Care Management Services and TCM Services for RHCs and FQHCs

In the CY 2020 PFS final rule (84 FR 62687), we finalized a policy allowing suppliers paid under the PFS to concurrently bill care management codes that were previously restricted from being billed with TCM for services billed under the PFS. This included allowing concurrent billing of TCM with 14 HCPCS codes, as well as CPT codes 99490 and 99491, which describe CCM services furnished under the PFS. However, we did not extend this policy to care management services furnished in RHCs or FQHCs at that time.

Consistent with changes made in the CY 2020 PFS final rule for care management services billed under the PFS, for CY 2022, we are proposing to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided that all requirements for billing each code are met. This would include the services described by HCPCS codes G0511 (*General Care Management for RHCs and FQHCs only*) and G0512 (*Psychiatric CoCM code for RHCs and FQHCs only*), which both describe a service period of one calendar month. We believe that when medically necessary, these services may complement each other rather than substantially overlapping or duplicating services since TCM services are furnished once within 30 days of a patient's discharge, whereas CCM services require a more comprehensive care management plan, care coordination and ongoing clinical care, and CoCM services describe care management services specifically for behavioral health conditions. We note that under this proposal, time and effort could not be counted more than once.

4. Proposed Conforming Technical Changes to 42 CFR 405.2466

In the November 6, 2020 **Federal Register**, we published the ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with request for comment (85 FR 71145 through 71147) (hereinafter referred to as the November 6, 2020 IFC). In the November 6, 2020 IFC, we implemented section 3713 of the CARES Act (Pub. L 116–136, March 27, 2020), which established Medicare Part B coverage and payment for a COVID–19 vaccine and its administration.

As we discussed in that rule (85 FR 71147), section 3713 of the CARES Act added the COVID–19 vaccine and administration to section 1861(s)(10)(A) of the Act in the same subparagraph as the influenza and pneumococcal vaccines and their administration. Therefore, the Medicare allowed amount and billing processes for COVID–19 vaccinations are similar to those in place for influenza and pneumococcal vaccinations across provider/supplier settings. The amendments made to section 1861(s)(10)(A) of the Act were effective on the date of enactment, that is, March 27, 2020, and apply to a COVID–19 vaccine beginning on the date that such vaccine is licensed under section 351 of the PHS Act (42 U.S.C. 262). A list of vaccines and their effective dates are updated as they are available and located on the CMS website at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies*. Although there were regulations updated to reflect the changes set forth by the CARES Act, we inadvertently did not revise the specific regulation text that applies to RHCs and FQHCs.

Therefore, consistent with the changes described above, we are proposing to make conforming technical changes to the applicable RHC and FQHC regulations in 42 CFR part 405, subpart X, specifically:

- At § 405.2466, Annual reconciliation, we are proposing to amend paragraph (b)(1)(iv) to include the COVID–19 vaccine in the list of vaccines and their administration that would be paid at 100 percent of Medicare reasonable cost.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)—Telecommunications Technology

1. Revising the Definition of an RHC and FQHC Mental Health Visit

a. Payment Rules for RHC and FQHC Visits and for Medicare Telehealth Services

Section 1861(aa)(1) of the Act defines RHC services as physicians' services and such services and supplies that are furnished as an incident to a physician's professional service, and items and services as well as certain vaccines and their administration. It also includes services furnished by a PA, NP, clinical psychologist, or clinical social worker and services and supplies furnished as incident to these services as would otherwise be covered if furnished by a physician or incident to a physician's service. In the case of an RHC in an area with a home health agency shortage, part-time or intermittent nursing care and related medical supplies may be furnished by a registered professional nurse or licensed practical nurse to a homebound individual under certain conditions. Section 1861(aa)(3) of the Act defines FQHC services to include the specified RHC services and preventive services as well as required primary preventive health services.

As previously stated, RHC and FQHC visits are defined as medically-necessary, face-to-face encounters between a patient and an RHC or FQHC practitioner, during which time one or more RHC or FQHC qualifying services are furnished. Services furnished must be within the practitioner's state scope of practice, and only services that require the skill level of the RHC or FQHC practitioner are considered RHC or FQHC visits. The RHC and FQHC payment is based on the costs of all services, except in certain circumstances, such as vaccines and their administration.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary primary health care services, and qualified preventive health services, furnished by an RHC practitioner. Medicare pays 80 percent of the RHC AIR, subject to a payment limit. Services furnished incident to an RHC professional service are included in the AIR and are not billed as a separate visit. The professional component of a procedure is usually a covered service, but is not a stand-alone billable visit. The costs of covered services provided incident to a

[59] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html.*

[60] *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html.*

[61] *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

billable visit may be included on the RHC cost report.

FQHCs are paid 80 percent of the lesser of the FQHC's charge or the FQHC PPS payment rate. Except for grandfathered tribal FQHCs, the FQHC PPS payment rate reflects a base rate that is the same for all FQHCs, a geographic adjustment based on the location where services are furnished, and other applicable adjustments. The FQHC PPS rate was established based on the aggregate of FQHC total costs, and is updated yearly by the FQHC market basket.

Under the PFS, Medicare makes payment to professionals and other suppliers for physician's services, certain diagnostic tests, and some preventive services. Section 1834(m) of the Act specifies for Medicare telehealth services paid under the PFS, the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe ''face-to-face'' services but are furnished using audio/video, real-time communication technology instead of in-person (82 FR 53006). Section 1834(m) of the Act also specifies conditions related to which professionals can be paid by Medicare for their professional services furnished via telehealth (referred to as distant site practitioners) and the originating site (both setting of care and geography) where a beneficiary is located while receiving telehealth services furnished remotely by the physician or practitioner through a telecommunications system. The regulation text at 42 CFR 410.78 describes a process for adding or deleting services to the list of Medicare telehealth services through the annual PFS rulemaking process and defines what technology may be used to furnish the service.

Under the permanent authority provided under section 1834(m)(4)(C)(ii) of the Act, RHCs and FQHCs, like hospitals, physician offices, and other sites, are authorized to serve as originating sites for eligible telehealth services. As defined in section 1834(m)(4)(C)(i) of the Act, the originating site is where the eligible telehealth individual is located at the time the service is furnished via a telecommunications system. As defined in section 1834(m)(4)(A) of the Act, the distant site is where the physician or practitioner is located at the time the service is provided via a telecommunications system. Originating sites are paid an originating site facility fee that is billed using HCPCS code Q3014 and is assigned a rate of $27.02 for CY 2021.

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) (Pub. L. 116–136, March 27, 2020) directs the Secretary to establish Medicare payment for telehealth services when RHCs and FQHCs serve as the distant site during the public health emergency (PHE) for COVID–19. Separately, section 3703 of the CARES Act expanded CMS' emergency waiver authority to allow for a waiver of any of the statutory telehealth payment requirements under section 1834(m) of the Act for telehealth services furnished during the PHE. Specifically, section 1834(m)(8)(B) of the Act, as added by the CARES Act, requires that the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site during the PHE for the COVID–19 pandemic. The payment methodology outlined in the CARES Act requires that rates shall be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. CMS established rates based on the average amount for all PFS telehealth services on the telehealth list, weighted by volume. RHCs and FQHCs bill for these Medicare telehealth services using HCPCS code G2025 and the rate for CY 2021 is $99.45. The temporary authority under section 1834(m)(8) of the Act to pay RHCs and FQHCs for furnishing distant site Medicare telehealth services expires when the PHE for the COVID–19 pandemic is terminated. While they will continue to be able to serve as an originating site for Medicare telehealth services, the payment mechanism for the professional services of RHC and FQHC practitioners will be FQHC and RHC payments under the established methodology, that is the RHC AIR or the FQHC PPS.

b. Adoption of Telehealth Technologies for Mental Health Care

While not specific to RHC and FQHC telehealth services provided during the PHE, according to MedPAC's report, Telehealth in Medicare after the Coronavirus Public Health Emergency,[62] there were 8.4 million telehealth services paid under the PFS in April 2020, compared with 102,000 in February 2020. MedPAC also reported that during focus groups held in the summer of 2020, clinicians and beneficiaries supported continued access to telehealth visits with some combination of in-person visits. They cited benefits of telehealth, including improved access to care for those with physical impairments, increased convenience from not traveling to an office, and increased access to specialists outside of a local area. In their annual beneficiary survey, over 90 percent of respondents who had a telehealth visit reported being ''somewhat'' or ''very satisfied'' with their video or audio visit, and nearly two-thirds reported being ''very satisfied.''

Widespread use of telecommunications technology to furnish services during the PHE has illustrated interest within the medical community and among Medicare beneficiaries in furnishing and receiving care through the use of technology beyond the PHE. During the PHE for COVID–19 pandemic, RHCs and FQHCs, much like other provider types, have had to change how they furnish care in order to meet the needs of their patients, and use of the temporary authority to bill Medicare for PFS telehealth services has been widely utilized by RHCs and FQHCs during the PHE. This shift in how care is furnished has prompted us to reevaluate the regulations regarding visit requirements for encounters between an RHC or FQHC patient and an RHC or FQHC practitioner to ensure that they reflect contemporary medical practice.

Recently enacted legislation modified the circumstances under which Medicare makes payment for mental health services furnished via telehealth technology under the PFS following the PHE. Division CC, section 123 of the Consolidated Appropriations Act of 2021 (CAA) (Pub. L. 116–260, December 27, 2020) removed the domestic geographic originating site restrictions and added the home of the individual as a permissible originating site for telehealth services billed under the PFS when furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. This change correlates with a growing acceptance of the use of technology in the provision of mental health care. Clinicians furnishing telepsychiatry services at Massachusetts General Hospital Department of Psychiatry during the PHE observed several advantages of the virtual format for furnishing psychiatric services, noting that patients with psychiatric pathologies that interfere with their ability to leave home (for example, immobilizing depression,

[62] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

anxiety, agoraphobia, and/or time-consuming obsessive-compulsive rituals) were able to access care more consistently since eliminating the need to travel to a psychiatry clinic can increase privacy, and therefore, decrease stigma-related barriers to treatment, potentially bringing care to many more patients in need, as well as enhanced ease of scheduling, decreased rate of no-shows, increased understanding of family and home dynamics, and protection for patients and practitioners with underlying health conditions.[63]

These findings are consistent with our analysis of Medicare claims data that indicate that use of interactive communication technology for mental health care is likely to continue to be in broad use beyond the circumstances of the pandemic. According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth under the PFS during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time; however, utilization was still higher than it was prior to the PHE. In contrast, Medicare claims data suggests that for mental health services both permanently and temporarily added to the Medicare Telehealth list, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given this information, broad acceptance in the public and medical community, and the relatively stable Medicare utilization of services during the entire COVID–19 pandemic, we believe use of interactive communication technology in furnishing mental health care is becoming an established part of medical practice, very likely to persist well after the COVID–19 pandemic, and available across the country under Medicare statute for the range of professionals furnishing mental health care and paid under the PFS.

c. Revising the Definition of an RHC and FQHC Mental Health Visit

We believe beneficiaries receiving mental health services from RHC and FQHC practitioners should have the same access to mental health care delivered via telecommunications technology as beneficiaries receiving services from practitioners paid under the PFS. We also believe that disruptions in access to mental health care from trusted practitioners can be particularly problematic for Medicare beneficiaries, especially when it results in fragmented care. However, absent changes in the definition of mental health visits, RHCs and FQHCs would no longer be paid by Medicare for mental health care services delivered via telecommunications technology and would likely resume furnishing solely in-person, face-to-face mental health visits after the PHE, thereby removing the ability for beneficiaries to be able to receive these services from RHC/FQHC practitioners if furnished via interactive communication technology.

Because the definitions of RHC and FQHC services, as specified in sections 1861(aa)(1) and (3) of the Act, respectively, refer specifically to physicians' services, and services that would be physicians' services, but are instead furnished by certain other types of practitioners, we believe it would be consistent to align policies to provide access to services furnished by RHCs and FQHCs similar to PFS services, where appropriate and within statutory requirements. To ensure that beneficiaries can access services furnished by RHCs and FQHCs in a manner similar to mental health services under the PFS after the PHE, we believe it is appropriate to consider modifying our regulatory definition of a mental health visit to provide for remote access to RHC and FQHC services. Therefore, to avoid both the inequities in access to modes of care, and to avoid potentially problematic interruptions to care or the negative consequences of fragmented care, for CY 2022, we are proposing to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time telecommunications technology, but only when furnishing services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.

Additionally, similar to the discussion of proposals for mental health services furnished under the PFS, as described in section II.D. of this proposed rule, we believe that mental health telehealth services furnished via audio-only communications technology would increase access to care, especially in areas with poor broadband infrastructure and among patient populations that either are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. Therefore, in order to align with proposals related to use of audio-only telecommunications technology to furnish similar mental health services under the PFS, we are proposing to allow RHCs and FQHCs to furnish mental health visits using audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. We note that the decision related to a service being furnished via telecommunications technology should be a patient-centered choice and that providers/practitioners should not force or impose services being furnished via telecommunications technology on beneficiaries who prefer to receive the services in-person. Additionally, some patients may prefer a hybrid whereby some mental health services are in person, but other times they are done using telecommunications technology. We believe that this decision should be based on the clinical judgment of the practitioner, in consideration of patient needs and preferences.

This proposed change would allow RHCs and FQHCs to report and be paid for mental health visits furnished via real-time, telecommunication technology in the same way they currently do when these services are furnished in-person. This proposed expansion of payable modes of mental health services furnished by RHCs and FQHCs corresponds with the expanded availability for professionals paid for Medicare Telehealth services under the PFS authorized by section 123 of the CAA and using the technology available for use for corollary services when paid under the PFS. This proposed revision would not allow RHCs or FQHCs to report visits furnished using asynchronous communications like email exchanges. Rather, RHCs and FQHCs would continue to report and be paid for furnishing medically necessary virtual communications services in accordance with the requirements for HCPCS code G0071 (83 FR 59686). Also, this proposed change would not allow RHCs and FQHCs to report Medicare telehealth services under section 1834(m) of the Act or be paid under the PFS since RHCs and FQHCs are not authorized to serve as distant site practitioners for Medicare telehealth services once the PHE for the COVID–19 pandemic has been terminated. In order to track utilization of mental health visits furnished using communication technology, we are proposing that RHCs and FQHCs would append the 95 modifier (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) in instances where the service was furnished using audio-video communication technology or a new

[63] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7347331/.*

service level modifier in cases where the service was furnished audio-only.

Additionally, we note that section 123 of the CAA also requires that there be an in-person service within 6 months prior to the furnishing of the telehealth service and at intervals thereafter as specified by the Secretary for mental health services furnished via Medicare telehealth under the PFS. We are seeking comment on whether we should consider a similar requirement for mental health services furnished by RHCs and FQHCs via telecommunications technology, or whether this requirement may be especially burdensome for beneficiaries receiving treatment at RHCs and FQHCs, particularly in rural areas. If we were to establish a similar requirement for RHC and FQHC mental health services, we could consider the proposal for Medicare telehealth services described in section II.D. of this proposed rule that there be an in-person service within 6 months prior to the furnishing of the telecommunications service and that an in-person service (without the use of telecommunications technology) be provided at least every 6 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, which would be documented in the patient's medical record, or whether we should defer to the clinical judgment of the practitioner on how often an in-person visit would be appropriate.

d. Regulatory Changes

We are proposing to revise the regulation at § 405.2463, to revise paragraph (a)(1)(i) to state that a mental health visit is a face-to-face (that is, in person) encounter (or, for mental health visits only, an encounter that meets the requirements under paragraph (b)(3)) between an RHC patient and an RHC practitioner. We are proposing to revise paragraph (b)(3) to define a mental health visit as a face-to-face encounter or an encounter where services are furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder. We are also proposing to revise § 405.2469, FQHC supplemental payments, to revise paragraph (d) by adding that a supplemental payment required under this section is made to the FQHC when a covered face-to-face (that is, in-person) encounter or an encounter where services are furnished using interactive, real-time, telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463.

C. Federally Qualified Health Centers (FQHCs) Payment for Tribal FQHCs—Comment Solicitation

1. Health Services to American Indians and Alaska Natives (AI/AN)

There is a special government-to-government relationship between the federal government and federally recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders and the U.S. Constitution. This government-to-government relationship forms the basis for federal health services to American Indians/Alaska Natives (AI/AN) in the U.S. In 1976, the Indian Health Care Improvement Act (IHCIA) (Pub. L. 94–437, September 30, 1976) amended the statute to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services to AI/ANs may be furnished by IHS operated facilities and programs and tribally-operated facilities and programs under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA) (Pub. L 93–638, January 4, 1975). According to the IHS Profile,[64] the IHS healthcare delivery system currently consists of 46 hospitals, with 24 of those hospitals operated by the IHS and 22 of them operated by tribes under the ISDEAA, as well as 492 health centers, 75 operated by IHS and 417 operated by tribes under the ISDEAA.

Payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, based on the previous year cost reports from federal and tribal hospitals. The IHCIA provided the authority for CMS (then HCFA) to pay IHS and tribal facilities for its outpatient hospital services to Medicare eligible patients, using an outpatient per visit rate (also referred to as the Medicare all-inclusive payment rate (AIR).

2. Federally Qualified Health Centers (FQHCs) Prospective Payment System (PPS)

FQHCs were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101– 508, November 5, 1990), and were effective beginning on October 1, 1991. They are facilities that furnish services that are typically furnished in an outpatient clinic setting. There are many FQHCs operated by IHS and tribes. The statutory requirements that FQHCs must meet to furnish services to Medicare beneficiaries are in section 1861(aa)(4) of the Act. All FQHCs are subject to Medicare regulations at 42 CFR part 405, subpart X, and 42 CFR part 491. Based on these provisions, the following three types of organizations that are eligible to enroll in Medicare as FQHCs:

- Health Center Program grantees: Organizations receiving grants under section 330 of the PHS Act (42 U.S.C. 254b).
- Health Center Program ''lookalikes'': Organizations that have been identified by the Health Resources and Services Administration as meeting the requirements to receive a grant under section 330 of the PHS Act, but which do not receive section 330 grant funding.
- Outpatient health programs or facilities operated by a Tribe or tribal organization under the ISDEAA, or by an urban Indian organization receiving funds under Title V of the IHCIA.

FQHCs are also entities that were treated by the Secretary, for purposes of Medicare Part B, as a comprehensive federally funded health center as of January 1, 1990 (see section 1861(aa)(4)(C) of the Act). Section 1834 of the Act was amended in 2010 by section 10501(i)(3)(A) of the Affordable Care Act by adding a new subsection (o), ''Development and Implementation of Prospective Payment System'' for FQHCs. Section 1834(o)(1)(A) of the Act requires that the system include a process for appropriately describing the services furnished by FQHCs, and establish payment rates based on such descriptions of services, taking into account the type, intensity, and duration of services furnished by FQHCs. It also stated that the new system may include adjustments (such as geographic adjustments) as determined appropriate by the Secretary. Section 1833(a)(1)(Z) of the Act, as added by the Affordable Care

[64] *https://www.ihs.gov/newsroom/factsheets/ihsprofile/.*

Act, requires that Medicare payment for FQHC services under section 1834(o) of the Act be 80 percent of the lesser of the actual charge or the PPS amount determined under section 1834(o) of the Act.

In accordance with the requirements in the statute, as amended by the Affordable Care Act, beginning on October 1, 2014, payment to FQHCs is based on the lesser of the national encounter-based FQHC PPS rate, or the FQHC's total charges, for primary health services and qualified preventive health services furnished to Medicare beneficiaries. The FQHC PPS rate is adjusted by the FQHC geographic adjustment factor (GAF), which is based on the Geographic Practice Cost Index used under the PFS. The FQHC PPS rate is also adjusted when the FQHC furnishes services to a patient that is new to the FQHC, and when the FQHC furnishes an IPPE or an AWV. Payment to the FQHC for a Medicare visit is the lesser of the FQHC's charges (as established by the G-code), or the PPS rate. The CY 2021 FQHC PPS rate is $176.45.

3. Grandfathered Tribal FQHCs

In the November 16, 2015 **Federal Register**, we published a final rule, entitled ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (referred to as CY 2016 PFS final rule). In that rule, we discuss the payment methodology and requirements finalized for grandfathered tribal FQHCs (80 FR 71089 through 71096). We stated that tribal facilities that met the conditions of § 413.65(m) on or before April 7, 2000, and had a change in their status on or after April 7, 2000, from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital, such that the organization no longer met the Medicare Conditions of Participation (CoPs) for Medicare-participating hospitals at § 482.12, the ''governing body'' of the facility could nevertheless seek to become certified as a grandfathered tribal FQHC.

In CY 2016 PFS final rule, we explained that a different structure was needed to maintain access to care for AI/AN populations served by the hospitals and clinics impacted by the provider-based rules at § 413.65, while also ensuring that the tribal clinics are in compliance with our health and safety rules. We recognized that a tribal clinic billing under an IHS hospital's CMS Certification Number (CCN), without any additional administrative or clinical relationship with the IHS hospital, could put that hospital at risk for noncompliance with their CoPs because the clinic had a separate governing body although still provider-based. We explained that the FQHC program provided an alternative structure that met the needs of these tribal clinics and the populations they served, while also ensuring the IHS hospitals were not at risk of being cited for non-compliance with the requirements with their CoPs (80 FR 71090).

As stated in § 405.2462(d)(1) a ''grandfathered tribal FQHC'' is a FQHC that is operated by a tribe or tribal organization under the ISDEAA; was billing as if it were provider-based to an IHS hospital on or before April 7, 2000 and is not currently operating as a provider-based department of an IHS hospital. We refer to these tribal FQHCs as ''grandfathered tribal FQHCs'' to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000. There are 7 ''grandfathered tribal FQHCs''.

Under the authority in section 1834(o) of the Act to include adjustments determined appropriate by the Secretary, we revised §§ 405.2462 and 405.2464 to pay these grandfathered tribal FQHCs on the Medicare outpatient per visit rate as set annually by the IHS, that is, the AIR and not the FQHC PPS payment rates (80 FR 71089). Payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, based on the previous year cost reports from federal and tribal hospitals. The outpatient per visit rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(m), or a ''grandfathered'' tribal FQHC as described at § 405.2462(d)(1). There is an outpatient per visit AIR for Medicare visits in Alaska and a separate outpatient per visit AIR for Medicare visits in the lower 48 states. For CY 2021, the outpatient per visit rate for Medicare visits in Alaska is $662 and $414 in the lower 48 states (85 FR 86940). There are no grandfathered tribal FQHCs in Alaska because the tribes operate the hospitals, not IHS. We note that IHS does not operate any hospitals or facilities in Hawaii or the territories, and thus no rates are set, in those localities.

As we discussed in CY 2016 PFS final rule, the payment rate is not adjusted by the FQHC GAF; for new patients, annual wellness visits, or initial preventive physical examinations; or annually by the FQHC PPS market basket, as further adjustments would be unnecessary and/or duplicative of adjustments already made by IHS in deriving the rate. Comparatively, the FQHC PPS rate established by CMS is $176.45. The reimbursement is the lesser of the charges or the IHS AIR rate. We stated as part of the CY 2016 PFS final rule that we would monitor future costs and claims data of these tribal clinics and reconsider options as appropriate.

4. Paying all IHS- and Tribally-Operated Outpatient Clinics the AIR

CMS established a Tribal Technical Advisory Group (TTAG) in 2004 to provide advice and input to CMS on policy and program issues impacting AI/AN populations served by CMS programs. Although not a substitute for formal consultation with Tribal leaders, the TTAG enhances the government-to-government relationship and improves increased understanding between CMS and Tribes. The TTAG has subject specific subcommittees that meet on a regular basis in order to be more effective and perform in-depth analysis of Medicare, Medicaid, CHIP, and the Health Insurance Marketplace policies that have Tribal implications. The TTAG is comprised of 17 representatives: An elected Tribal leader, or an appointed representative from each of the 12 geographic areas of the IHS delivery system and a representative from each of the national Indian organizations headquartered in Washington DC—the National Indian Health Board, the National Congress of American Indians, and the Tribal Self-Governance Advisory Group. The American Recovery and Reinvestment Act of 2009 section 5006(e)(1), which became effective July 1, 2009, mandates that TTAG shall be maintained within CMS and added two new representative's positions: A representative and alternate from a national urban Indian health organization (National Council of Urban Indian Health) and a representative and alternate from the IHS.

The TTAG has requested [65] that CMS amend its Medicare regulations to make all IHS and tribally-operated outpatient

[65] *https://www.nihb.org/tribalhealthreform/wp-content/uploads/2020/06/TTAG-letter-to-CMS-requesting-IHS-rate-for-all-tribal-clinics-06.10.2020.pdf.*

facilities eligible for payment at the IHS Medicare outpatient per visit rate/AIR. The TTAG explained that outpatient clinics, which are otherwise similar to grandfathered tribal FQHCs, are paid at different rates depending upon whether they meet the requirements as a ''provider based facility,'' a ''grandfathered tribal FQHC,'' a non-grandfathered tribal FQHC, or none of the above. They believe that the rates vary based on the Medicare regulatory definition, rather than the actual costs of the outpatient clinic. There are varying payment differentials among Medicare enrolled providers and suppliers under the authorities of the SSA. For example, Ambulatory Surgical Centers are paid differently than hospital outpatient departments; which are paid differently whether they're under the under the outpatient prospective payments system or a located in a critical access hospital.

The TTAG also questioned the need for grandfathered tribal FQHCs to file cost reports. Specifically, the TTAG stated that the FQHC cost reports have no relationship to the IHS Medicare outpatient per visit rate/AIR paid to grandfathered tribal FQHCs, as they use hospital cost reports in setting the rate. Therefore, they stated, the FQHCs should only need to file a cost report to the extent necessary to support payment for non-FQHC services that are reimbursed outside the Medicare outpatient per visit rate/AIR. We note that under section 1815(a) of the Act, providers participating in the Medicare program are required to submit financial and statistical information to achieve settlement of costs relating to health care services rendered to Medicare beneficiaries. Under the FQHC PPS, Medicare payment for FQHC services is the lesser of the FQHC PPS rate or the charges on the claim. In the establishment of the FQHC PPS, the statute does not exempt FQHCs from submitting cost reports. In addition, Medicare payments for the reasonable costs of the influenza and pneumococcal vaccines and their administration, allowable graduate medical education costs, and bad debts are determined and paid through the cost report. The FQHC market basket also uses information from the FQHC cost report to determine the cost share weights, which reflect the relative costs of input expenses that FQHCs face in order to provide FQHC services. Having a full picture of the costs of providing care by grandfathered FQHCs is important so that CMS can be sure that payments are adequate.

5. Comment Solicitation

We appreciate the TTAG's concerns with ensuring that CMS make appropriate payments among the clinics for similar services and the impact this has on tribal Medicare beneficiaries and ensuring that access to healthcare is available and equitable and we take these concerns seriously. However, we have insufficient information necessary to evaluate the costs and benefits of potential changes to these policies. Therefore, we would like to solicit comment on the TTAG's request for CMS to amend its Medicare regulations to make all IHS- and tribally-operated outpatient facilities/clinics eligible for payment at the Medicare outpatient per visit rate/AIR, regardless of whether they were owned, operated, or leased by IHS.

We seek information on the kinds of and number of facilities or clinics that could potentially enroll in Medicare as an FQHC, or are already an FQHC paid under the FQHC PPS, and if these clinics are freestanding or provider-based to expand on information provided by the IHS Profile. We seek information regarding the relative operating costs of IHS- and tribally-operated outpatient clinics compared to non-tribal FQHCs, stakeholder feedback and supporting evidence to address whether or why payment set at the IHS AIR would be more appropriate than payment rate under the FQHC PPS. Further, we seek comment on how the IHS AIR, which is based upon a limited number of hospital cost reports, relates to costs in such clinics and the kinds of services that the clinics furnish. Finally, we seek comment on the concerns that the AI/AN community may have on issues regarding access or inequity care in situations where a payment differential exists.

While, we have information on grandfathered tribal FQHCs and the outpatient hospital cost reports, we do not have any information specific to the composition of IHS and tribal facilities. For example, if the facility is not enrolled in Medicare as an FQHC or is not provider based to a hospital, is it a physician practice? It would be helpful to know how the facilities are organized and related. Are there other options for enrolling as different types of providers or suppliers?

As increasing the rate would increase payments from the Medicare Trust Fund, we are also seeking comment on the magnitude of that payment change and whether any program integrity concerns would be present with the increased payment. We also request comments on FQHC services that are paid through the cost report, like influenza, pneumococcal, and COVID–19 vaccinations and GME and how that impacts the request to not file cost reports. As stated above, having a full picture of the costs of providing care is important so that CMS can be sure that payments are adequate. Are these services included in the IHS/AIR?

We are also seeking input on other potential uses of the adjustment authority under section 1834(o)(1)(A) of the Act which provides that the FQHC PPS may include adjustments determined appropriate by the Secretary. For example, we could consider TTAG's request on the expansion of the payment policy finalized in the CY 2016 PFS final rule for grandfathered tribal FQHCs to all Tribally-operated outpatient clinics. Alternatively, we could develop a payment adjustment applicable to IHS- and tribally-operated outpatient clinics based on the cost differential reported in their cost reports when compared to non-IHS outpatient clinics, or non-provider-based clinics, if such differentials exist and would be interested in specific comments about appropriate adjustments to the FQHC PPS rate for clinics that are enrolled as FQHCs. We seek comment on other potential ways to determine whether the costs associated with furnishing services to AI/AN are uniquely greater than other clinics within the confines of the FQHC PPS outlined in section 1834(o)(1) of the Act.

D. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B and Determination of ASP for Certain Self-Administered Drug Products

1. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.806)

a. Overview and Summary

Section 1927(b)(3)(A)(iii)(I) of the Act requires manufacturers with a Medicaid drug rebate agreement to report Average Sales Price (ASP) data as specified in section 1847A of the Act. Some manufacturers without Medicaid drug rebate agreements voluntarily submit ASP data for their single source drugs or biologicals that are payable under Part B; however, other manufacturers without Medicaid drug rebate agreements do not voluntarily submit such data. Without manufacturer reported ASP data, CMS cannot calculate the ASP payment limit, and consequently, payment is typically based on Wholesale Acquisition Cost (WAC).

Consistent with section 1847A(c)(3) of the Act and our regulations at

§ 414.804(a)(2), the ASP is net of price concessions. However, consistent with the definition of WAC at section 1847A(c)(6)(B) of the Act, the WAC is not net of price concessions, and thus, is nearly always, and sometimes, significantly, higher than ASP. Drugs with payment allowances based on WAC may have greater ''spreads'' between acquisition costs and payment than drugs for which there is an ASP-based payment allowance, which, in turn, may: (1) Incent the use of the drug based on its spread rather than on purely clinical considerations; (2) result in increased payments under Medicare Part B; and (3) increase beneficiary cost sharing.

Section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 401'') amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Section 401(b)(2) also amended section 1847A(c)(6)(A) of the Act to permit the Secretary to exclude repackagers [66] from the definition of ''manufacturer'' for purposes of the ASP reporting requirement in section 1847A(f)(2) of the Act, if the Secretary determines appropriate.

Section 401(b)(1) also adds provisions to section 1847A of the Act addressing confidentiality, audit and verification provisions; civil money penalties for misrepresentation, late reporting, and reporting of false information; and increasing oversight and enforcement provisions. These provisions largely track the statutory provisions in section 1927(b) of the Act that apply to the reporting of ASP by manufacturers with Medicaid drug rebate agreements. Additionally, section 401(d) requires HHS Office of the Inspector General (OIG) to submit a report on the accuracy of ASP submissions to Congress by January 1, 2023.

Finally, section 401 amended section 1927(b) of the Act to clarify that for Part B ASP reporting, drugs would include items, services, supplies, and products that are payable under Medicare Part B as a drug or biological.

We are proposing regulatory changes to implement the new reporting requirements at 42 CFR, part 414, subpart J.

b. Reporting Requirements for Manufacturers Without a Medicaid Drug Rebate Agreement

Starting with calendar quarters beginning on January 1, 2022, manufacturers will be required to report ASP for drugs and biologicals payable under Medicare Part B consistent with the statutory requirements of section 1847A(f) of the Act, regardless of whether they have Medicaid drug rebate agreements. Our existing regulations at 42 CFR part 414, subpart J implement the ASP reporting requirements referenced in section 1847A(f)(1) of the Act, that is, the requirements of section 1927(b)(3) of the Act. Thus, the existing regulations at 42 CFR part 414, subpart J already set forth requirements for manufacturers with Medicaid drug rebate agreements to report their ASP information (and if required to make payment, WAC) each quarter.

Many manufacturers without Medicaid drug rebate agreements voluntarily submit ASP data consistent with these requirements. Whether obligated to report or voluntarily reporting, manufacturers are accustomed to the existing regulatory requirements at 42 CFR part 414 subpart J, and indeed, the methodology for reporting ASP reflected in these regulations does not currently distinguish between manufacturers with Medicaid drug rebate agreements and those without these agreements.

Because new section 1847A(f)(2) of the Act, as noted previously, largely parallels section 1927(b)(3) of the Act, and thus both manufacturers with Medicaid drug rebate agreements, as well as those without such agreements, will be subject to requirements already reflected in the existing regulations at subpart J, we do not believe it is necessary to propose substantial changes to the regulation text. For these reasons, our proposal to amend the regulations to reflect the new requirements of section 1847A(f)(2) of the Act seeks to preserve the status quo to the extent possible.

c. Definitions

As noted previously, the new section 1847A(f)(2) of the Act, as added by section 401(a), requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022 for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Section 401 also made a conforming amendment to the ASP reporting requirements applicable to manufacturers with Medicaid drug rebate agreements at section 1927(b)(3)(A)(iii) of the Act to specify that those reporting requirements also apply to items, services, supplies, and products that are payable under Part B as a drug or biological.

To implement this change, we propose to amend the definition of the term ''drug'' at § 414.802 to mean a drug or biological, and includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

Section 1847A(c)(6)(A) of the Act incorporates the definition of manufacturer at section 1927(k)(5) of the Act, except that section 401(b)(2) permits the Secretary to exempt repackagers from the definition of manufacturer, as determined appropriate, for purposes of section 1847A(f)(2) of the Act. However, no such exemption is provided for manufacturers with Medicaid drug rebate agreements (see the definition of manufacturer at § 447.502). Consequently, the current ASP data reporting includes submissions by repackagers.

To confirm the Medicare Payment Advisory Commission's (MedPAC's) assertion in their June 2017 report (available at *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf*) that many repackagers currently do not report ASP data, and thus inform our consideration of whether we should propose to exclude repackagers from the definition of manufacturers for purposes of section 1847A(f)(2) of the Act, we conducted an analysis to estimate the proportion of repackaged products in our existing ASP data. If our existing ASP data do not contain an appreciable

[66] The FDA has defined ''repackag[ing],'' for purposes of drug establishment registration, as ''the act of taking a finished drug product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug.'' 21 CFR 207.1. The FDA has defined ''repack[ager]'' for purposes of drug establishment registration as the person who owns or operates an establishment that repacks a drug or drug package.'' Id. For more information about repackaging, please see FDA guidance documents, including a January 2017 Guidance for Industry titled, ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities,'' available at *https://www.fda.gov/media/90978/download* and the FDA's January 2018 Guidance for Industry titled, ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application,'' available at *https://www.fda.gov/files/drugs/published/Mixing-Diluting-or-Repackaging-Biological-Products-Outside-the-Scope-of-an-Approved-Biologics-License-Application.pdf.*

proportion of repackaged products, it may be appropriate to exclude repackagers from the definition of manufacturer for this limited purpose. However, if repackaged products comprise an appreciable proportion of our existing ASP data, we would reasonably anticipate this trend to follow under the new requirements, and in such a scenario, it would not be appropriate to exclude repackagers from the definition of manufacturer for purposes of section 1847A(f)(2) of the Act because excluding their sales could distort the ASP.

To effectuate this analysis, we obtained a list of National Drug Codes (NDCs) of repackaged drugs from the United States Food and Drug Administration (FDA).[67] We also obtained a list of labeler codes for which the manufacturers have Medicaid drug rebate agreements.[68] We then performed a crosswalk both of these to our composite file of ASP data submissions to segregate our composite file of ASP data submissions into four categories:

(1) Repackaged products for which ASP data submissions were required (that is, manufacturers with Medicaid drug rebate agreements);

(2) Repackaged products for which ASP data submissions were voluntary (that is, for manufacturers without Medicaid drug rebate agreements);

(3) Non-repackaged products for which ASP data submissions were required; and

(4) Non-repackaged products for which ASP data submissions were voluntary.

We estimate that, of all 6319 products for which we currently receive ASP data submissions (the sum of categories (1)–(4) above), repackaged products accounted for 271 (4.29 percent) of these products. Additionally, repackaged products accounted for 137 (2.51 percent of) products for which ASP data submissions were required, and 134 (15.23 percent of) products for which ASP data were voluntarily submitted.

Additionally, we conducted another analysis to estimate: (1) The number of new ASP submissions we can expect as a result of the new requirements under section 401; and (2) the proportion of those submissions that involve repackaged products. To effectuate this analysis, we obtained a crosswalk of NDCs and Healthcare Common Procedure Coding System (HCPCS) codes that includes the NDCs and HCPCS codes of items for which ASP reporting is not currently required.[69] We supplemented this crosswalk by adding HCPCS codes with NDCs that are payable under Part B, but not already reflected in the crosswalk.[70] We then identified [71] and removed from the crosswalk all of the products contained in our composite file of ASP data submissions and those HCPCS codes that are non-covered under Medicare Part B. Adding the results of this analysis to the results of categories two and four from the prior analysis (that is, repackaged and non-repackaged products for which ASP submissions were voluntary), we estimate there will be 6994 total products for which manufacturers will now be required to submit ASP data. We then compared this number to the FDA's list of repackaged products in the previous analysis, and found that of the 6994 products for which manufacturers will be required to submit ASP data, 223 (3.19 percent) are repackaged products. Further, we estimate 6114 products for which their manufacturers did not previously (voluntarily) submit ASP data and will now be required to do so under the new reporting requirements of section 401. Of these, 89 (1.46 percent) are repackaged products.

These data do not persuade us that it is necessary to exempt repackagers from the new reporting requirements under section 401 at this time. Our current operational process to verify the accuracy of manufacturers' reported ASP data does not distinguish: (1) Products on the basis of repackaging, and (2) manufacturers who are required to report ASP data from those who do so voluntarily.

Each month, CMS reviews ASP data submissions at the NDC level (and for products without NDCs, the manufacturer's product code). Previously, we have not required manufacturers to identify which products are repackaged as part of these submissions. Exempting repackagers from the new requirements of section 1847A(f)(2) of the Act would significantly increase our administrative burden because we would have to undergo an additional quality check for each NDC from a different database for which data are submitted as part of our operational process to verify the accuracy of manufacturers' reported ASP data. Moreover, for products without NDCs, our ability to determine if these products are repackaged (without manufacturer attestation) to that effect is significantly limited. Finally, any such attestation would require a data source for us to verify the accuracy of the attestation, and no such data source currently exists.

These additional checks could, in turn, significantly increase the time it takes for us to calculate and display on our website the volume-weighted ASP payment limits. Additionally, we are concerned that exempting repackagers from the new reporting requirements could lead to a gap in ASP reporting, meaning that ASPs could be distorted to the extent that certain sales are carved out of the reporting requirement through the use of repackagers. Consequently, in order to maintain consistency and integrity of the ASP data for those manufacturers with and without Medicaid drug rebate agreements, we do not believe it is appropriate to exclude repackagers from the requirements of section 401 at this time. However, we may propose to exempt repackagers in the future, if warranted.

We solicit comment on this approach.

In summary, we propose to modify the definition of drug at § 414.802 to include any item, service, supply or product that is payable under Part B as a drug or biological. We are not proposing to exclude repackagers from the definition of manufacturer for purposes of the reporting requirements at section 1847A(f)(2) of the Act.

d. Civil Money Penalties

As amended by section 401(b), section 1847A(d)(4)(A) of the Act specifies the penalties associated with misrepresentations in the reporting of the manufacturer's ASP for a drug or biological. Consistent with our existing regulation at § 414.806, if the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied.

New sections 1847A(d)(4)(B) and (C) of the Act, as added by section 401(b),

[67] *https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory*. We note that this list only included prescription drugs approved under a New Drug Application (NDA) or Abbreviated NDA (ANDA) and did not include biological products approved under a Biologics License Application (BLA) or devices.

[68] *https://data.medicaid.gov/Uncategorized/Drug-Manufacturer-Contacts/uex2-n56q/data*. This link has all labeler codes with effective date and termination date, if applicable. If there is a termination date, the code was not active as of that date.

[69] *https://www.dmepdac.com/palmetto/PDACv2.nsf/DID/FFYLYC1WVL* Accessed April 12, 2021, using the April 2021 files.

[70] We note that such products were spread across the second and fourth categories in the prior analysis.

[71] We used the April 2021 Alpha-Numeric HCPCS codes files available at *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update*. We selected HCPCS codes with a coverage code of S (column AE), which indicates that the product is non-covered by the Medicare statute.

apply civil money penalties for failure to report timely and accurate ASP data for manufacturers without Medicaid drug rebate agreements, consistent with the civil money penalties found at sections 1927(b)(3)(C)(i) and (ii) of the Act for manufacturers with Medicaid drug rebate agreements. Our current regulations at § 414.806 refer to section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173, December 8, 2003), as specifying the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

We propose to amend § 414.806 to reflect the new provisions specifying penalties for manufacturers without Medicaid drug rebate agreements and to provide some technical changes to streamline the regulations text. Specifically, we propose to do the following:

- Add paragraph (a), labeled as ''Misrepresentation'', moving the existing regulatory language at § 414.806 specific to misrepresentation to this paragraph;
- Remove the sentence which reads, ''If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to $10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied,'' since the previous sentence in the regulations text already references the statutory provision for this language;
- Add paragraph (b), labeled as ''Failure to provide timely information or the submission of false information'';
- Add paragraph (b)(1) to clarify that the existing language at § 414.806 regarding civil money penalties for failure to submit timely information or for the submission of false information applies to manufacturers with a Medicaid drug rebate agreement;
- Remove the phrase ''as amended by section 303(i)(4) of the MMA''; and
- Add paragraph (b)(2) to reflect new sections 1847A(d)(4)(B) and (C) of the Act regarding civil money penalties for failure to submit timely information or for the submission of false information for manufacturers without a Medicaid drug rebate agreement.

We welcome comments on these proposals.

e. Summary of all Proposals

In summary, to implement the new reporting requirements for manufacturers without Medicaid drug rebate agreements, we are proposing to modify:

- The definition of drug at § 414.802; and
- The regulations describing civil money penalties at § 414.806.

We welcome comments on these proposals.

2. Determination of ASP for Certain Self-Administered Drug Products (§ 414.904)

a. Background

Drugs and biologicals payable under Medicare Part B fall into three general categories: those furnished incident to a physician's services (hereinafter referred to as ''incident to'') (section 1861(s)(2) of the Act), those administered via a covered item of durable medical equipment (DME) (section 1861(s)(6) of the Act), and others as specified by statute (for example, certain vaccines described in sections 1861(10)(A) and (B) of the Act). Payment limits for most drugs and biologicals separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Most drugs payable under Part B are paid under the ''incident to'' benefit under section 1861(s)(2) of the Act, which includes drugs and biologicals not usually self-administered by the patient.

Paragraphs (4)(A) and (6) of sections 1847A(b) of the Act require that the Medicare Part B payment amount for a single-source drug or biological be determined using all of the NDCs assigned to it. Section 1847A(b)(5) of the Act further states that the payment limit shall be determined without regard to any special packaging, labeling, or identifiers on the dosage form or product or package. In 2007, CMS issued a program instruction (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*), as permitted under section 1847A(c)(5)(C) of the Act, stating that the payment limit for a single source drug or biological will be based on the pricing information for products produced or distributed under the applicable FDA approval (such as a New Drug Application (NDA) or Biologics License Application (BLA)). Therefore, all versions of a single source drug or biological product (or NDCs) marketed under the same FDA approval number (for example, NDA or BLA, including supplements) are considered the same drug or biological, for payments made under section 1847A of the Act and are crosswalked to the same billing and payment code. This means that a self-administered version marketed under the same FDA approval is subject to the ASP reporting requirements and is not excluded from the payment limit calculation, even though Medicare does not make separate Part B payment for it. This is consistent with our longstanding policy on the scope of the ASP reporting requirements. (Please see our final rule titled, ''Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007,'' published in the December 1, 2006 **Federal Register** (71 FR 69675)). The price of a drug or biological product that may be administered by the patient (that is, self-administered) may differ from versions that are administered incident to a physician's service, which may affect the ASP-based payment limit for drug or biological product's billing and payment code.

The HHS OIG conducted studies [72] [73] of payment-limit calculations for certain drugs paid under section 1847A of the Act. The OIG identified two highly utilized biological products for which there are both Part-B-covered (versions administered incident to a physician's service) and non-covered versions (those identified to be self-administered) for which the NDCs were marketed under the same FDA approval number. OIG's studies found that when the ASPs of the self-administered versions are included in the payment limit calculation, the resulting payment limit is substantially higher than if the ASPs of only the incident-to versions had been included.

The OIG studies concluded that as a result, Medicare payment amounts were inflated, causing the program and its beneficiaries to pay an additional $366 million from 2014 through 2016 and $497 million from 2017 through 2018. They recommended that legislative changes be made to provide CMS the flexibility to determine when certain versions of a drug identified to be self-administered should be included in ASP payment limit calculations.

Section 405 of Division CC, Title IV of the CAA, 2021, amended section 1847A of the Act by redesignating

[72] *https://www.oig.hhs.gov/oei/reports/oei-12-17-00260.pdf*, accessed March 15, 2021.

[73] *https://www.oig.hhs.gov/oei/reports/OEI-BL-20-00100.pdf*, accessed March 15, 2021.

existing subsection (g) as subsection (h) and adding new subsection (g), which describes the Medicare Part B ASP payment-limit adjustment for certain drugs and biological products for which NDCs have been identified by the OIG to be self-administered and not covered under Medicare Part B. The new section 1847A(g)(1) of the Act directs OIG to conduct periodic studies to identify NDCs for drug or biological products that are identified to be self-administered for which payment may not be made under Part B pursuant to section 1861(s)(2) of the Act and that OIG determines should be excluded from the determination of the payment amount under section 1847A of the Act.

New section 1847A(g)(2) of the Act specifies that if the OIG identifies an NDC under section 1847A(g)(1) of the Act, it must inform the Secretary at such times as the Secretary may specify. Then the Secretary shall, to the extent appropriate, apply as the payment limit for the applicable billing and payment code the lesser of: (1) The payment allowance that would be determined under section 1847A of the Act if the NDC for the identified drug or biological product were excluded from the calculation; or (2) the payment limit otherwise determined under section 1847A of the Act without application of section 1847A(g) of the Act. In other words, the Medicare payment limit for a drug or biological product's billing and payment code in these circumstances would be the lesser of the payment limit determined including the NDCs identified to be self-administered and the payment limit determined after excluding the NDCs identified to be self-administered (hereinafter referred to as the ''lesser-of payment methodology'').

Although section 1847A(g)(1) of the Act provides us with discretion in whether to apply the lesser-of methodology to billing and payment codes that include self-administered versions identified by the OIG (because we are directed to apply the methodology to the extent deemed appropriate), new section 1847A(g)(3) of the Act, requires the application of the lesser-of methodology to the two billing and payment codes identified in the OIG's July 2020 report titled, ''Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars,'' (available at *https://oig.hhs.gov/oei/reports/OEI-BL-20-00100.asp*) (hereinafter referred to as ''OIG's July 2020 report'')) beginning July 1, 2021. To meet the implementation date required by this provision, we applied the lesser-of methodology to the payment limit calculations for the billing and payment codes representing Cimzia® (certolizumab pegol) and Orencia® (abatacept), details on these calculations are described in this section. In a memorandum providing supplemental information on the OIG July 2020 report, the OIG provided specific NDCs that the report identified: 00003–2188–11, 00003–2188–51, 00003–2814–11, 00003–2818–11, 50474–0710–79, 50474–0710–81. The lesser-of methodology was applied to these billing and payment codes for the July 2021 ASP Drug Pricing Files and crosswalks along with program instructions in a change request (CR) at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files*.

We propose to codify the new requirements of section 1847A(g) of the Act at § 414.904. Our proposals described in the next section specify when the application of the lesser-of methodology would be appropriate, describe how we will apply the lesser-of payment methodology to billing and payment codes that OIG has identified pursuant to studies described in section 1847A(g)(1) of the Act, and codify the approach we used for the certolizumab pegol and abatacept billing and payment codes.

b. Identification of Billing and Payment Codes to Which the Lesser-of Policy Will Be Applied

As noted previously, section 1847A(g)(1) of the Act directs OIG to conduct periodic studies to identify NDCs for drug or biological products that are self-administered and for which payment is not made under Part B. Section 1847A(g)(2) of the Act specifies that if OIG makes an identification under section 1847A(g)(1) of the Act, OIG informs CMS at such times as we may specify, and in such an event, we apply the lesser-of methodology to the extent deemed appropriate. We propose that when the OIG conducts a periodic study, OIG informs us at the time the study becomes are publicly available. CMS will obtain the NDCs identified by the OIG study described in section 1847A(g)(1) of the Act. However, if the specific NDCs are not available in the OIG study report, we will request OIG provide documentation of the identified NDCs to CMS.

To allow operational time for assessment and application of the lesser-of methodology, we believe it is reasonable that the application of the lesser-of methodology be reflected beginning in the ASP pricing file two quarters following the OIG study publication. For example, if the OIG study becomes available to the public in the first quarter of the calendar year, the lesser-of methodology would be applied to the payment limit calculation of the applicable billing and payment code in the third quarter ASP pricing file (in other words, the July ASP pricing file) and each quarter thereafter.

c. Calculation of Payment Allowance Using the Lesser-of Payment Methodology

Sections 1847A(g)(2) and (g)(3) of the Act set forth the lesser-of payment methodology for applicable billing and payment codes with NDCs for certain drug or biological products identified by the OIG as self-administered products for which payment may not be made under this part because such products are not covered under section 1861(s)(2) of the Act. In this section, we describe how we propose to apply the lesser-of methodology. We propose to codify this methodology, which we currently use for the billing and payment codes that describe certolizumab pegol and abatacept, and which we propose to use for billing and payment codes for which OIG identifies a drug or biological product with NDCs identified to be self-administered as described in section 1847A(g)(1) of the Act.

The ASP payment limit calculation is described in section 1847A(b)(6) of the Act and codified at § 414.904(b)(2)(ii) and (c)(2)(ii), which specifies that for a billing and payment code, the volume-weighted average of the average sales prices reported by the manufacturer is determined by:

- Computing the sum of the products (for each NDC assigned to such drug products) of:
  - ++ The manufacturer's average sales price determined by the Secretary without dividing such price by the total number of billing units for the NDC for the billing and payment code; and
  - ++ The total number of units sold; and
- Dividing the sum determined under (A) by the sum of by the sum of the products (for each NDC assigned to such drug products) of
  - ++ The total number of units specified sold; and
  - ++ The total number of billing units for the NDC for the billing and payment code.

When applying the lesser-of methodology described in 1847A(g)(2) and (g)(3) of the Act, we propose to make two calculations as described in section 1847A(b)(6) of the Act: (1) The ASP payment limit for the billing and payment code, excluding the NDCs that have been identified by the OIG study (that is, excluding the ASPs for those NDCs as well as the units of such NDCs

sold in the quarter); and (2) the ASP payment limit for the billing and payment code, including such NDCs' ASPs and units sold. The calculation resulting in the lower payment limit will be used as the payment limit for the applicable billing and payment code for that quarter's ASP pricing files. We propose to apply the lesser-of methodology to the billing and payment codes containing OIG-identified products each quarter when determining ASP payment limits.

New section 1847A(g) of the Act does not change ASP reporting requirements, and consistent with section 1847A(f)(1) of the Act and, beginning January 1, 2022, section 1847A(f)(2) of the Act, manufacturers must continue to report ASP data for all NDCs of the drug or biological product. Under new section 1847A(g) of the Act, ASP data for all NDCs under the same FDA approval application (for example, NDA or BLA, including any supplements) are required to carry out the lesser-of calculations for the purposes of determining the payment limit for the billing and payment code. Even if the resulting payment limit does not reflect the ASPs or units sold of self-administered versions of a product identified by the OIG, the manufacturer must continue to report those versions' ASPs and units sold to the Secretary.

The implementation of the lesser-of methodology is not expected to be associated with substantial administrative costs. We plan to incorporate methodology in the current operational process that is used to determine ASP payment limits each quarter. The OIG found that Medicare and its beneficiaries would have saved a combined $497 million on certolizumab pegol and abatacept over 2 years (2017–2018) if such a methodology had been in place.

d. Exceptions

We further propose that the application of the lesser-of methodology is deemed appropriate in all cases in which OIG identifies a drug or biological product in a periodic study described in section 1847A(g)(1) of the Act and made publicly available, unless the drug or biological product is in short supply.[74] As stated in the OIG's July 2020 report, CMS expressed concern about potential impact on beneficiary access if certain versions identified to be self-administered were excluded from the ASP payment limit calculation. Because of potential for drug shortages that may affect patient care, beneficiary and provider access, and drug prices for providers, we would consider it not appropriate to apply the lesser-of methodology when a product is in short supply. Similar to the average manufacturer price (AMP) price substitution provision in section 1847A(d)(3)(C) of the Act (codified in § 414.904(d)(3)), we propose to add § 414.904(d)(4)(ii) to specify that we will not apply the lesser-of methodology (that is, we will determine the payment allowance including all NDCs of the drug or biological product) if the drug and dosage form(s) represented by the billing and payment code are reported by the Drug Shortage list established under section 506E of the Federal Food, Drug, and Cosmetic Act (FFDCA) at the time that ASP payment limits are being finalized for the next quarter. However, we propose that this exception to the application of the lesser-of methodology would not apply in the case of the billing and payment codes for certolizumab pegol and abatacept because section 1847A(g)(3) of the Act does not provide us with the same discretion as section 1847A(g)(2) of the Act. Thus, for these applicable billing and payment codes we will always apply the lesser-of methodology. We recognize that NDCs identified by an OIG study described in section 1847A(g)(1) or (g)(3) of the Act may change, for example, because of a manufacturer change. In the event that the manufacturer of an OIG-identified product simply redesignates the NDC for its product, we believe the new NDC also would meet the same criteria defined in the OIG study. In this circumstance, we expect that the product labeling would not contain substantial changes regarding the redesignated NDC. Therefore, we propose to add § 414.904(d)(4)(iv) to codify the application of the lesser-of methodology such that the manufacturer-reported pricing data associated with redesignated NDCs will be used in the lesser-of methodology in the same way as the original OIG-identified NDC.

Once an OIG study identifies self-administered versions of a drug or biological product, there may be subsequent FDA approvals of other products with the same active ingredient, such as new syringe sizes, new types of injector syringes, generic formulations, biosimilar biological products, or interchangeable biological products. For example, this would include the situation in which the current manufacturer of certolizumab pegol or abatacept obtains a supplemental FDA approval for a new version of the product. Similarly, this would also include the situation in which another manufacturer gains FDA approval of a product with the same active ingredient as an OIG-identified self-administered version. We believe that provisions at new section 1847A(g) of the Act would require a new OIG study as described in section 1847A(g)(1) of the Act in order for us to apply the lesser-of methodology to the drug or biological product.

e. Summary

In summary, to implement new section 1847A(g) of the Act, we are proposing to:

- Add § 414.904(d)(4) to codify the lesser-of payment methodology and define when the application of the lesser-of methodology would first be reflected in the ASP pricing file following the OIG study publication; and
- Describe the lesser of methodology at § 414.904(d)(4)(iv).
- Describe exceptions to application of the lesser-of methodology at § 414.904(d)(4)(ii).
- Clarify application of the lesser-of methodology for billing and payment code described under section 1847A(g)(3) of the Act at § 414.904(d)(4)(iii).
- Describe the application of the lesser-of methodology to redesignated NDCs of those identified in the OIG studies at § 414.904(d)(4)(v).

We welcome comments on these proposals.

E. Medicare Part B Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act

1. Background

For most drugs that are payable under Medicare Part B, payment-limit amounts are determined using the methodology in section 1847A of the Act. In many cases, the payment-limit amount is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. Additionally, small molecule drugs payable under Medicare Part B using the methodology in section 1847A of the Act fall into two broad, mutually exclusive categories: (1) Multiple source drugs, and (2) single source drugs. These terms are defined in sections 1847A(c)(6)(C) and (D) of the Act, respectively.

[74] Our regulation at § 414.904(d)(3)(ii)(C) in reference to AMP price substitution refers to drugs ''identified by FDA as being in short supply.'' The current AMP price substitution policy for shortages is consistent with the policy discussed here, as we interpret the phrase ''identified by FDA as being in short supply'' at § 414.904(d)(3)(ii)(C) to mean the list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

In most cases, the distinction between multiple source drugs and single source drugs is straightforward. We published program instructions in 2007 (available at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*) that address how these distinctions are made. However, a subset of drugs that are approved by the FDA under New Drug Applications (NDAs) are approved through the pathway established under section 505(b)(2) of the FFDCA (Pub. L. 75–717, June 25, 1938) (hereinafter referred to as ''section 505(b)(2) drug products''). For section 505(b)(2) drug products, the distinction between multiple source drugs and single source drugs can be less straightforward.

The drug approval pathway established under section 505(b)(2) of the FFDCA (hereinafter referred to as ''the section 505(b)(2) pathway'') provides an avenue for applications that contain full reports of investigations of safety and effectiveness, where at least some of the information needed for an approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference or use.[75] An application submitted under the section 505(b)(2) pathway (hereinafter referred to as a ''section 505(b)(2) application'') may rely either on the FDA's findings of safety, effectiveness, or both, for an already-FDA-approved drug product or on published literature, provided that: (1) Such reliance is scientifically justified, and (2) the section 505(b)(2) application complies with applicable statutory and regulatory requirements, including, but not limited to, patent certification, if appropriate. Unlike a generic drug product approved under an Abbreviated New Drug Application (ANDA), a section 505(b)(2) drug product is not required to have the same FDA-approved labeling as the labeling for the already-FDA-approved drug product(s) upon which the section 505(b)(2) application relied. (For more information, see the FDA's May 2019 guidance titled, ''Determining Whether to Submit an ANDA or a 505(b)(2) Application,'' available at *https://www.fda.gov/media/124848/download*.)

The number of section 505(b)(2) drug products approved each year has been growing, from about 40 per year from 2011 to 2016, to about 60 to 70 per year from 2017 to 2020. Approximately 10 to 20 percent of these section 505(b)(2) drug products are payable under Medicare Part B. Of these, some section 505(b)(2) drug products share substantial portions of the FDA-approved labeling with the approved drug product(s) upon which the section 505(b)(2) application relied, for example prescribing information on safety, efficacy, and pharmacokinetics. In some cases, the section 505(b)(2) drug product even shares substantial portions of labeling with generic drug products that are payable under Part B as multiple source drugs. Medicare Part B claims data from 2020 indicate that spending for some of these section 505(b)(2) drug products (that is, those that could be assigned to a multiple source drug code under the framework described below, but are instead currently assigned to a single source drug code) is substantially greater than that for the corresponding generic drug products assigned to a multiple source drug code. One example is a sterile injectable drug that was first approved as a lyophilized powder for reconstitution in a vial and later was approved through the section 505(b)(2) pathway as a concentrated liquid in a vial. Another example is a drug available as a lyophilized powder for reconstitution in a vial that was then approved through the section 505(b)(2) pathway as a ready-to-use intravenous (IV) solution in a bag. Analysis of 2020 claims data for the separately coded section 505(b)(2) drug product (that is, the ready-to-use IV solution) shows that Medicare spending per service unit was approximately eight times that of the corresponding products in the multiple source drug code. Moreover, in the July 2021 ASP Pricing File (available at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files*), the payment limit for the section 505(b)(2) drug product is 17.2 times the payment limit for the multiple source code, when adjusted for the different dose descriptors of each code. In another example, there were approximately 7.54 million allowed service units, representing approximately $1.38 million of allowed charges, for a multiple source drug code, but for the separately coded section 505(b)(2) drug product, over the same time-period there were approximately 1.08 million allowed service units, representing approximately $2.13 million in allowed charges. Calculating the allowed charges per allowed service unit, each service unit of the section 505(b)(2) drug product cost Medicare 10.78 times that of the corresponding products assigned to the multiple source drug code, costing Medicare an additional $1.93 million. In the July 2021 ASP Pricing File, the payment limit for the section 505(b)(2) drug product is 21.3 times the payment limit for the multiple source code.

Based on these observed data points, we are planning an additional analysis of spending on section 505(b)(2) drug products and potential savings to Medicare and Medicare beneficiaries that may be realized if certain section 505(b)(2) drug products were to be assigned to multiple source drug codes based on the framework described in section 3 of this preamble.

2. CY 2021 Proposal

In the CY 2021 PFS proposed rule, we proposed to codify our long-standing approach to determine whether a section 505(b)(2) drug product is described by an existing multiple source drug code, or if the section 505(b)(2) drug product would be assigned to a single source drug code. In that proposal, we explained generally how information about the section 505(b)(2) drug product's active ingredient(s), drug product name (this refers to nomenclature of the drug product as found in the United States Pharmacopeia—National Formulary (USP–NF) and nomenclature as found in title of the FDA-approved labeling), and description; labeling information; and ordering (prescribing) and clinical use would factor into a determination. Commenters on our proposal in the CY 2021 PFS proposed rule (primarily manufacturers) stated that the proposal conflicted with both the Medicare statute and the FDA's therapeutic equivalence (TE) ratings,[76] [77] and would impair access for patients, underpay providers, and stifle innovation. Several commenters from beneficiary advocate and provider organizations generally repeated the same points, although some commenters expressed support for curbing drug prices, particularly if the proposal did not affect patient access. Several commenters appeared to take a middle ground that conditionally supported the proposals, particularly if more detail could be provided and if effects on patient access were considered. Several commenters supported the proposals without conditions. Several commenters expressed that we should provide more

[75] Regulations at 21 CFR 314.3 define ''Right of Reference or Use'' to mean the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an NDA, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

[76] As published in the FDA's ''Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations'' available at *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.*

[77] See also 21 CFR 314.3(b) for definitions of ''therapeutic equivalents'' and related terms, as well as *https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.*

detail about the decision framework and the determination process.

Some commenters on the CY 2021 PFS proposed rule requested that we provide more details about the process by which certain section 505(b)(2) drug products would be assigned to multiple source drug codes. Commenters requested that we include more detail on how factors described in the CY 2021 PFS proposal, (for example, differences in the active ingredient and labeling) may be interpreted and which drug products might be affected. Commenters also requested that we provide the public more time to assess a more detailed proposal as well as an opportunity, such as through future rulemaking, for public input both on the proposal and on decisions about specific drug products.

Several commenters stated that if we move forward with the CY 2021 proposal, we should exclude products with ''meaningful differences'' from the policy and encouraged us to continue an approach ''that allows for innovation, competition, and ultimately more therapeutic choices for Medicare beneficiaries.'' We recognize that some section 505(b)(2) drug products have clear differences in factors such as safety, efficacy, or pharmacokinetics, which would not result in the assignment of the product to the existing multiple source drug code. The framework discussed in the next section would address situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code, and therefore, would not be assigned to the existing multiple source drug code.

In response to commenters' requesting more detail about our proposed approach and to delay finalizing a decision, we did not finalize our proposals in the CY 2021 PFS proposed rule regarding section 505(b)(2) drug products. We stated that the delay would allow time for CMS to further consider this issue. As part of our further consideration, we are soliciting comment on a more detailed framework (hereinafter referred to as ''the framework'') for determining when a section 505(b)(2) drug product is a multiple source drug under section 1847A(c)(6)(C) of the Act.

The framework is consistent with program instruction published in 2007, which addressed how we would assign ''single source drugs'' and ''biological products'' using a multi-step process. However, this program instruction did not expressly address how we would assign multiple source drugs. The program instruction uses the term ''drug'' at the billing and payment code level when discussing single source drugs in the same way that the discussion in this preamble uses the term ''drug'' in reference to multiple source drugs. Development of standards for identifying multiple source drugs (that is, the framework) would add to the 2007 program instruction and provide detail about an approach to Medicare Part B payment for section 505(b)(2) drug products.

The framework described in the next section aims to build off the current CMS policy for assigning drug products to billing and payment codes by describing detailed standards for determining whether a section 505(b)(2) drug product corresponds to an existing multiple source drug code. We are not proposing to adopt the framework at this time. Rather, we are seeking comment on the framework to inform future policy making.

3. The Framework

The framework is a determination process to identify when section 505(b)(2) drug products without an FDA TE rating to an existing drug product payable under Part B correspond to an existing multiple source drug code for the purpose of payment under Medicare Part B. The framework would provide additional detail about the decision-making process and increase transparency about potential determinations resulting from the framework.

The first portion of the framework would compare certain qualities of the section 505(b)(2) drug product with drug products already assigned to an existing multiple source drug code.[78] This includes comparison of the: (1) Active ingredient(s); (2) dosage form (if part of the drug product name); (3) salt form; and (4) other ingredients in the drug product formulation. The drug product assessment could result in a match or non-match designation. Section 505(b)(2) drug products receiving a match designation in the first portion of the framework would continue to a verification step. This step would compare the pharmacokinetic and clinical studies of the section 505(b)(2) drug product's FDA-approved labeling with those of the drug products already assigned to an existing multiple source code. Finally, a determination would be made as to whether the section 505(b)(2) drug product could be assigned to the existing multiple source code.

For full details on the framework, please see *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.*

We are soliciting comment on:

- The framework and how it aligns with the statutory definitions of single source and multiple source drugs in section 1847A(c)(6)(C) and (D) of the Act, respectively;
- How the framework distinguishes situations in which a section 505(b)(2) drug product is not described by an existing multiple source drug code; and
- The potential impacts of the framework on Medicare beneficiaries, the government, and other stakeholders.

F. Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 218(b) of the Protecting Access to Medicare Act (Pub. L. 113–93, April 1, 2014) (PAMA) amended Title XVIII of the Act to add section 1834(q) of the Act directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. We have taken steps to implement this program over several years, and codified the AUC program in our regulations at 42 CFR 414.94. In CY 2020, we began conducting an educational and operations testing period for the claims-based reporting of AUC consultation information, which has been extended through CY 2021.

The CY 2016 PFS final rule with comment period (80 FR 70886) addressed the initial component of the new Medicare AUC program, specifying applicable AUC. In the CY 2016 PFS final rule with comment period, we established an evidence-based process and transparency requirements for the development of AUC, defined provider-led entities (PLEs) and established the process by which PLEs may become qualified to develop, modify or endorse AUC. The first list of qualified PLEs was posted on the CMS website at the end of June 2016 at which time their AUC libraries became specified applicable AUC for purposes of section 1834(q)(2)(A) of the Act.

The CY 2017 PFS final rule (81 FR 80170) addressed the second component of this program, specification of qualified clinical decision support mechanisms (CDSMs). In the CY 2017 PFS final rule, we defined CDSM, identified the requirements CDSMs must meet for qualification, including preliminary qualification for mechanisms documenting how and when each requirement is reasonably

[78] These assignments are published as part of the ASP NDC–HCPCS Crosswalk Files available at *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files.*

expected to be met, and established a process by which CDSMs may become qualified. We also defined applicable payment systems under this program, specified the first list of priority clinical areas, and identified exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services. The first list of qualified CDSMs was posted on the CMS website in July 2017.

The CY 2018 PFS final rule (82 FR 53190) addressed the third component of this program, the consultation and reporting requirements. In the CY 2018 PFS final rule, we established the start date of January 1, 2020 for the Medicare AUC program for advanced diagnostic imaging services. Specifically, for services ordered on and after January 1, 2020, we established that ordering professionals must consult specified applicable AUC using a qualified CDSM when ordering applicable imaging services, and furnishing professionals must report AUC consultation information on the Medicare claim. We further specified that the AUC program will begin on January 1, 2020 with a year-long educational and operations testing period during which time AUC consultation information is expected to be reported on claims, but claims would not be denied for failure to include proper AUC consultation information. We also established a voluntary period from July 2018 through the end of 2019 that ordering professionals who are ready to participate in the AUC program may consult specified applicable AUC through qualified CDSMs and communicate the results to furnishing professionals; and furnishing professionals who are ready to do so may report AUC consultation information on the claim at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf*.

Additionally, to incentivize early use of qualified CDSMs to consult AUC, we established in the CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstances Policy for the Transition Year final rule with comment period and interim final rule (hereinafter ''CY 2018 Quality Payment Program final rule''), a high-weight improvement activity for ordering professionals who consult specified AUC using a qualified CDSM for the Merit-based Incentive Payment System (MIPS) performance period that began January 1, 2018 (82 FR 54193).

In the CY 2019 PFS final rule (83 FR 59452), we made further additions and clarifications to the AUC program requirements. We added independent diagnostic testing facility (IDTF) to the definition of applicable settings under § 414.94(b). We also clarified that the furnishing professionals (including provider or supplier entities furnishing advanced diagnostic imaging services in an applicable setting, paid for under an applicable payment system) are required to report AUC consultation information on the claims as specified under § 414.94(k). We established significant hardship exception criteria and process under § 414.94(i)(3) to be specific to the AUC program and independent of other Medicare programs. We specified under § 414.94(j)(2) that when delegated by the ordering professional, clinical staff under the direction of the ordering professional may perform the AUC consultation with a qualified CDSM. Finally, we announced our intention to use G-codes and modifiers to report AUC consultation information on the Medicare claims. In 2020, in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19) (PHE for COVID–19), the educational and operations testing period was extended through CY 2021.

1. Background

AUC present information in a manner that links a specific clinical condition or presentation; one or more services; and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual clinical presentation. For purposes of this program, AUC is a set or library of individual AUC. Each individual criterion is an evidence-based guideline for a particular clinical scenario based on a patient presenting symptoms or condition.

AUC need to be integrated as seamlessly as possible into the clinical workflow. CDSMs are the electronic portals through which clinicians access the AUC during the patient workup. They can be standalone applications that require direct entry of patient information, but may be more effective when they are integrated into electronic health records (EHRs). Ideally, practitioners would interact directly with the CDSM through their primary user interface, thus minimizing interruption to the clinical workflow.

2. Statutory Authority

Section 218(b) of the PAMA added a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directed the Secretary to establish a program to promote the use of AUC. Section 1834(q)(4) of the Act requires ordering professionals to consult with specified applicable AUC through a qualified CDSM for applicable imaging services furnished in an applicable setting and paid for under an applicable payment system; and payment for such service may only be made if the claim for the service includes information about the ordering professional's consultation of specified applicable AUC through a qualified CDSM.

3. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, and each component has its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2) of the Act); (2) identification of mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3) of the Act); (3) AUC consultation by ordering professionals, and reporting on AUC consultation by January 1, 2017 (section 1834(q)(4) of the Act); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5) of the Act). We did not identify mechanisms for consultation by April 1, 2016. Therefore, we did not require ordering professionals to consult CDSMs or furnishing professionals to report information on the consultation by the January 1, 2017 date.

a. Establishment of AUC

In the CY 2016 PFS final rule with comment period, we addressed the first component of the Medicare AUC program under section 1834(q)(2) of the Act—the requirements and process for establishment and specification of applicable AUC, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term ''provider-led entity'' and finalizing requirements for the rigorous, evidence-based process by which a PLE would develop AUC, upon which qualification is based, as provided in section 1834(q)(2)(B) of the Act and in the CY 2016 PFS final rule with comment period. Using this process, once a PLE is qualified by us, the AUC that are developed, modified or endorsed by the qualified PLE are considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act. We defined PLE to include national professional medical societies, health systems, hospitals, clinical practices and collaborations of such entities such as the High Value Healthcare Collaborative or the National Comprehensive Cancer Network.

Qualified PLEs may collaborate with third parties that they believe add value to their development of AUC, provided such collaboration is transparent. We expect qualified PLEs to have sufficient infrastructure, resources, and the relevant experience to develop and maintain AUC according to the rigorous, transparent, and evidence-based processes detailed in the CY 2016 PFS final rule with comment period.

In the same rule, we established a timeline and process under § 414.94(c)(2) for PLEs to apply to become qualified. Qualified PLEs are listed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html* (OMB Control Number 0938–1288).

b. Mechanism for AUC Consultation

In the CY 2017 PFS final rule, we addressed the second major component of the Medicare AUC program—the specification of qualified CDSMs for use by ordering professionals for consultation with specified applicable AUC under section 1834(q)(3) of the Act, along with relevant aspects of the definitions under section 1834(q)(1) of the Act. This included defining the term CDSM and finalizing functionality requirements of mechanisms, upon which qualification is based, as provided in section 1834(q)(3)(B) of the Act and in the CY 2017 PFS final rule. We defined CDSM as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition. Tools may be modules within or available through certified EHR technology (as defined in section 1848(o)(4) of the Act) or private sector mechanisms independent from certified EHR technology or a mechanism established by the Secretary.

In the CY 2017 PFS final rule, we established a timeline and process in § 414.94(g)(2) for CDSM developers to apply to have their CDSMs qualified. Qualified CDSMs are listed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html* (OMB Control Number 0938–1315).

c. AUC Consultation and Reporting

In the CY 2018 PFS final rule, we addressed the third major component of the Medicare AUC program—consultation with applicable AUC by the ordering professional and reporting of such consultations under section 1834(q)(4) of the Act. We established a January 1, 2020 effective date for the AUC consultation and reporting requirements for this program. We also established a voluntary period during which early adopters could begin reporting limited consultation information on Medicare claims from July 2018 through December 2019. During the voluntary period, there is no requirement for ordering professionals to consult AUC or furnishing professionals to report information related to the consultation. On January 1, 2020, the program began with an educational and operations testing period and during this time, we have continued to pay claims whether or not they correctly include AUC consultation information. Ordering professionals must consult specified applicable AUC through qualified CDSMs for applicable imaging services furnished in an applicable setting, paid for under an applicable payment system and ordered on or after January 1, 2020; and furnishing professionals must report the AUC consultation information on the Medicare claim for these services ordered on or after January 1, 2020.

Consistent with section 1834(q)(4)(B) of the Act, we also established that the following information must be reported on Medicare claims for advanced diagnostic imaging services as specified in section 1834(q)(1)(C) of the Act and defined in § 414.94(b), furnished in an applicable setting as defined in section 1834(q)(1)(D) of the Act, paid for under an applicable payment system as defined in section 1834(q)(4)(D) of the Act, and ordered on or after January 1, 2020: (1) The qualified CDSM consulted by the ordering professional; (2) whether the service ordered would or would not adhere to specified applicable AUC, or whether the specified applicable AUC consulted was not applicable to the service ordered; and (3) the NPI of the ordering professional (if different from the furnishing professional).

Section 1834(q)(4)(C) of the Act provides for exceptions to the AUC consultation and reporting requirements in the case of: A service ordered for an individual with an emergency medical condition, a service ordered for an inpatient and for which payment is made under Medicare Part A, and a service ordered by an ordering professional for whom the Secretary determines that consultation with applicable AUC would result in a significant hardship. In the CY 2017 PFS final rule, we adopted a regulation at § 414.94(h)(1)(i) to specify the circumstances under which AUC consultation and reporting requirements are not applicable and in the CY 2019 PFS final rule, we updated the significant hardship exception criteria to be specific to the AUC program and independent of other programs. An ordering professional experiencing any of the following when ordering an advanced diagnostic imaging service is not required to consult AUC using a qualified CDSM, and the claim for the applicable imaging service is not required to include AUC consultation information. Significant hardship exceptions under § 414.94(i)(3) include: Insufficient internet access; EHR or CDSM vendor issues; or extreme and uncontrollable circumstances.

We remind readers that, consistent with section 1834(q)(4)(A) of the Act, ordering professionals must consult AUC for every applicable imaging service furnished in an applicable setting and paid under an applicable payment system unless a statutory exception applies.

Section 1834(q)(4)(D) of the Act specifies the applicable payment systems for which AUC consultation and reporting requirements apply. In the CY 2017 PFS final rule, we defined applicable payment system to reflect the statutory requirements in § 414.94(b) as: (1) The PFS established under section 1848(b) of the Act; (2) the PPS for hospital outpatient department services under section 1833(t) of the Act; and (3) the ambulatory surgical center payment system under section 1833(i) of the Act.

Section 1834(q)(1)(D) of the Act specifies the applicable settings in which AUC consultation and reporting requirements apply: A physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other ''provider-led outpatient setting determined appropriate by the Secretary.'' In the CY 2017 PFS final rule, we added this definition to § 414.94(b). As noted above, we expanded that definition to add an IDTF in the CY 2019 PFS final rule.

d. Identification of Outliers

The fourth component of the Medicare AUC program is specified in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement that applies for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Because we established a start date of January 1, 2020 for AUC consultation and reporting requirements, we did not identify any outlier ordering professionals by that date. As such,

implementation of the prior authorization component is delayed. However, we did finalize in the CY 2017 PFS final rule the first list of priority clinical areas to guide identification of outlier ordering professionals as follows:

- Coronary artery disease (suspected or diagnosed).
- Suspected pulmonary embolism.
- Headache (traumatic and non-traumatic).
- Hip pain.
- Low back pain.
- Shoulder pain (to include suspected rotator cuff injury).
- Cancer of the lung (primary or metastatic, suspected or diagnosed).
- Cervical or neck pain.

We will use future rulemaking to establish the methodology for the identification of outlier ordering professionals who would eventually be subject to a prior authorization process when ordering advanced diagnostic imaging services.

4. Proposals for Continuing Implementation

a. Proposed Clarification of AUC Program Scope

i. Modified Orders

Updates or modifications to orders for advanced diagnostic imaging services may be warranted in certain situations once the beneficiary is under the care of the furnishing professional. Unless they are also serving as the ordering professional, furnishing professionals may not consult AUC on behalf of or in place of the ordering professional. The Medicare Benefit Policy Manual (BPM) (Pub. L. 100–02) addresses situations where the furnishing professional performs imaging services that differ from ordered services in chapter 15, sections 80.6.1–4. These BPM sections on modified orders state that when an interpreting physician determines that a different or additional imaging service not included on the order should be performed, the interpreting physician or testing facility generally may not perform the test until a new order from the treating physician/practitioner has been received. If the treating physician/practitioner cannot be reached to change or obtain a new order, the interpreting physician or testing facility may furnish the additional imaging service under the following circumstances, as documented in the patient's medical record: The treating physician/practitioner could not be reached, the ordered test is performed and an additional diagnostic test is medically necessary because of the abnormal result of that test, delaying performance of the additional test would have an adverse effect on the patient's care, the result of the additional test is communicated to and used by the treating physician/practitioner in the patient's treatment, and the interpreting physician/practitioner documents in the report the reasons for the additional testing.

When the furnishing professional performs additional imaging services not reflected on the order under these circumstances, we do not believe it would be appropriate to consider them to be acting as an ordering professional such that an AUC consultation would be needed. Instead, we believe the furnishing professional in these situations is the interpreting physician/practitioner who is exercising their professional judgment to provide the ordering professional with additional diagnostic test results for use in managing the patient's care. Additionally, they are doing so only because, after performing the ordered test and determining that additional testing is expedient given the results of that test, the ordering professional cannot be reached to request a modified or additional order. Given the conditions under which these additional imaging services are performed, we propose that when the furnishing professional for an advanced diagnostic imaging service performs one or more additional services under the circumstances described in chapter 15, section 80.6.2–4 of the BPM, neither the ordering professional nor the furnishing professional are required to consult AUC for the additional service(s). In these situations, the AUC consultation information from the original order is to be reported on the claim line for the additional service(s). Where the furnishing professional modifies the order for an advanced diagnostic imaging service without obtaining a new order from the ordering professional, the AUC consultation information provided by the ordering professional with the original order should be reflected on the Medicare claim to demonstrate that the requisite AUC consultation occurred. Because the BPM instructions state that the interpreting physician or testing facility generally may not perform a modified or new test until a new order from the treating physician/practitioner has been received, we expect situations where AUC consultations do not occur for new or modified orders to be infrequent.

ii. Extreme and Uncontrollable Circumstances Hardship Exception

In the CY 2019 PFS final rule, we describe extreme and uncontrollable circumstances to include disasters, natural or man-made, that have a significant negative impact on healthcare operations, area infrastructure or communication systems. We also explain these may include areas where events occur that have been designated by FEMA as a major disaster or a public health emergency declared by the Secretary. To further clarify, these circumstances are events that are entirely outside the control of the ordering professional that prevent the ordering professional from consulting AUC through a qualified CDSM. We believe the hardship criteria under this program are similar to other programs such as the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), particularly the flexibility that is given to clinicians to identify what they consider to be extreme and uncontrollable circumstances.

The PHE for COVID–19 has been in effect since January 27, 2020. Stakeholders have described challenges in continuing to prepare for the payment penalty phase of the AUC program due to resource reallocation resulting from the PHE. Some stakeholders have explained that all health technology projects unrelated to the PHE were halted, including projects that impact establishing or updating health IT systems that enable AUC consultation through qualified CDSMs. Stakeholders have also indicated that human resources were reallocated to focus on responding to the PHE. Additionally, we recognize that practitioners have been heavily impacted in their own practice of medicine to respond to the PHE and provide treatment to patients which may have prevented them from focusing on and participating in the educational and operations testing period to prepare for the payment penalty phase. While we are continuing to move forward in implementing the AUC program, we want to assure stakeholders that they may attest to a significant hardship under the AUC program due to extreme and uncontrollable circumstances due to the PHE for COVID–19, and such an attestation may be used as needed by ordering practitioners throughout the PHE. Furthermore, as the AUC program progresses into the payment penalty phase, self-attestation for a significant hardship exception will continue to be available for ordering professionals experiencing extreme and uncontrollable circumstances due to the PHE. We also recognize that ordering professionals may experience significant

hardships related to or resulting from the PHE that extend beyond the date the PHE expires and note that AUC program exceptions will continue to be available for such significant hardships as defined at § 414.94(i)(3).

b. Claims Processing

As we move ahead to implement the payment penalty phase of this program, we must address additional operational and administrative issues. We explain these issues here, and our assessments and proposals for addressing them. We are soliciting comments on whether additional scenarios require our consideration, and whether the proposed solutions adequately address issues raised by stakeholders. We are soliciting any additional information stakeholders may offer to assist us in developing claims processing system edits or other measures to ensure that only appropriate claims are subject to AUC claims processing edits. The AUC program will be fully implemented when we have the necessary edits established in the claims processing system and we begin using those edits to deny Medicare claims that fail to report the required AUC consultation information. Therefore, we need to find workable solutions that allow the AUC program to accurately pay and deny claims using the information available on Medicare claims, while working within the limitations of the Medicare claims processing system. The identification of claims that are or are not subject to the Medicare AUC Program must be precise to avoid inadvertently denying claims that should be paid. Because implementation of this program establishes edits for advanced diagnostic imaging claims, the inadvertent denial of claims would disproportionately impact radiologists, hospital outpatient departments and freestanding imaging centers. Also, as we have noted previously, the AUC program is unique in that the burden of consulting AUC and providing AUC consultation information to the furnishing professional falls on the ordering professional, yet the claims that are denied for failing to report AUC consultation information are for services furnished and billed by the professionals and facilities that furnish advance diagnostic imaging.

Two main Medicare claim types are subject to claims processing edits in the AUC program. These are the CMS–1500 and its electronic equivalent (referred to here as the practitioner claim) submitted by physicians and practitioners, ASCs, and IDTFs, and the UB–04, also called the CMS–1450, (referred to here as the institutional claim) submitted by hospital outpatient departments and on-campus and off-campus provider-based departments. These claim types differ in the data elements they contain; therefore, claims processing edits will not be identical across claim types.

We have already issued partial claims processing instructions (CR11268, Transmittal 2404) [79] to support the educational and operations testing period. We established HCPCS Level III G-codes for furnishing professionals to report which CDSM was consulted. We also established HCPCS modifiers for furnishing professionals to report adherence, non-adherence and not applicable AUC consultation responses on the same claim line as the corresponding G-code. Both G-codes and modifiers are applicable to practitioner and institutional claims. We established additional HCPCS modifiers for furnishing professionals to report situations in which the ordering professional is not required to consult AUC. These modifiers are reported on the same claim line as the code for the advanced diagnostic imaging procedure since a G-code would not be reported. We also established a procedure code list that identifies the advanced diagnostic imaging codes that are subject to the AUC program. Based on a review of CY 2020 Medicare claims (noting for readers that during this year the AUC program was only in the education and operations testing phase with no payment penalties), we estimate between 9–10 percent of all claims subject to the AUC program reported information sufficient to be considered compliant with the program, which means that 90–91 percent of claims would not be considered compliant with AUC program requirements. In other words, if the claims processing systems edits had been in place for the payment penalty phase, only 9–10 percent of claims subject to the AUC program would have been paid as opposed to being denied or rejected. An additional 6–7 percent of claims subject to the AUC program included some relevant information, which demonstrates an awareness of the AUC program among these billing entities; but the claims did not include all of the necessary AUC consultation information that will ultimately be required for the claim to be paid.

i. Ordering Professional NPI

There are locations on both the practitioner and institutional claim types to report the NPI of the ordering professional. The institutional claim uses the K3 segment and the practitioner claim uses the referring professional field. However, to fully implement the AUC program, we must establish a claims processing edit to require these fields to be populated on all advanced diagnostic imaging claims subject to the AUC program.

In addition, there currently are situations in which multiple advanced diagnostic imaging services ordered by more than one ordering professional may be reported on a single claim. This would not be workable for purposes of reporting AUC consultation information because the referring professional field is reported at the claim-level and not at the claim line- or service-level for professional claims. Therefore, the furnishing professional will need to submit separate claims for the services ordered by each referring or ordering professional. In other words, only one ordering professional can be reported per claim.

ii. Critical Access Hospitals

As discussed in the CY 2018 PFS final rule with comment period (82 FR 53192), advanced diagnostic imaging services furnished in an outpatient department of a critical access hospital (CAH) are not subject to the AUC program because, in accordance with section 1833(q)(1)(D) of the Act, a CAH is not an applicable setting under the program. Therefore, we must identify these advanced diagnostic imaging services and allow them to bypass the AUC program claims processing edits. For institutional claims, we intend to apply the AUC program claims processing edits to type of bill 13x, which is used only for outpatient hospital settings. CAHs submit outpatient claims using type of bill 85x, rather than type of bill 13x.

In the CY 2019 PFS final rule (83 FR 59694), we further explained that because section 1834(q)(4)(B) of the Act clearly includes all claims paid under applicable payment systems without exclusion, the claims from both furnishing professionals and facilities must include AUC consultation information. We revised our regulation at § 414.94(k) to specify that AUC consultation information must be reported on Medicare claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. Prior to this revision, § 414.94(k) required furnishing professionals to report AUC consultation on the claim, without also specifying that facility claims must include the AUC consultation

[79] *https://www.cms.gov/files/document/r2404otn.pdf.*

information. In the CY 2019 PFS final rule, we explained that the AUC consultation information would be included on the practitioner's claim for the professional component (PC) of the service and on the provider's or supplier's claim for the facility portion or technical component (TC) of the service. Under § 414.94(k), the requirement to report AUC consultation information on the claim applies to both the PC and TC of the imaging services that are furnished in an applicable setting and paid under an applicable payment system. Section 1834(q)(4)(B) of the Act further specifies that the requirement to report AUC consultation information is specific to claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. We believe that all claims for advanced diagnostic imaging services, both the PC and TC, must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. However, if advanced diagnostic imaging services are not entirely furnished in an applicable setting, we believe that neither the PC nor TC claim should be required to include AUC consultation information. This ensures consistent application of the AUC consultation requirements across claims submitted for advanced diagnostic imaging services even when the PC and TC components of the service are furnished by different furnishing professionals. As such, we propose that claims submitted by physicians or practitioners for the PC of an advanced diagnostic imaging service when the TC was not furnished in an applicable setting would not be subject to the AUC program since the setting where the TC of the imaging service is furnished is not subject to the AUC program consultation and reporting requirements. If a physician or practitioner submits a claim for the PC of an advanced imaging service for which the TC was performed as an outpatient CAH service, there currently is not a systems-based way for us to recognize that the TC of the service was furnished by a CAH. Place of service codes reported on practitioner claims are not specific enough. We have not yet identified a way to segregate these claims and automatically allow them to bypass AUC program claims processing edits. Therefore, as discussed below, we propose to establish a separate HCPCS modifier that will be used to identify practitioner claims for advanced diagnostic imaging services that are not subject to the AUC program and that are not otherwise identified using the other AUC program modifiers designated to identify specific situations where the claims are not subject to the AUC program.

iii. Maryland Total Cost of Care Model

Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for which AUC consultation and reporting requirements apply are the PFS, the hospital OPPS and the ambulatory surgical center payment system. We define applicable payment system consistent with statute at § 414.94(b) and, as noted above, require AUC consultation information to be reported on Medicare claims for advanced diagnostic imaging services, both the PC and TC, furnished in an applicable setting and paid under an applicable payment system at § 414.94(k). Section 1834(q)(4)(B) of the Act specifies that the requirement to report AUC consultation information is specific to claims for advanced diagnostic imaging services furnished in an applicable setting and paid under an applicable payment system. We believe that all claims for the advanced diagnostic imaging services, both the PC and TC, must include the AUC consultation information when they are furnished both in an applicable setting and paid under an applicable payment system. Therefore, if both the PC and TC for advanced diagnostic imaging services are not paid under an applicable payment system, neither the PC nor TC claim is required to include AUC consultation information. This ensures consistent application of the AUC consultation requirements across claims submitted for advanced diagnostic imaging services even when the PC and TC components of the service are furnished by different furnishing professionals. Similar to claims for the PC of services for which the TC is furnished outside of an applicable setting, and because both practitioner and institutional claims are subject to the AUC program as discussed above, when the practitioner or institutional claim for the advanced imaging service is not subject to the AUC program (for example, payment is not made under an applicable payment system), the corresponding practitioner or institutional claim for the same imaging service is also not subject to the AUC program.

Stakeholders alerted CMS to concerns about whether advanced diagnostic imaging services furnished in hospitals participating in the Maryland Total Cost of Care Model would be subject to the AUC program. We appreciate that this has been brought to our attention and we seek comments on other models. Advanced diagnostic imaging services furnished in outpatient departments of Maryland hospitals that participate in the Hospital Payment Program within the Maryland Total Cost of Care Model are not subject to the AUC program because these services are not paid under an applicable payment system (Maryland hospitals that receive payments under the Hospital Payment Program within the Maryland Total Cost of Care Model are not paid under the OPPS). Because these services are not subject to the AUC program requirements when furnished in a hospital paid under the Hospital Payment Program within the Maryland Total Cost of Care Model, as opposed to an applicable payment system, we propose that the PCs of these advanced diagnostic imaging services, when billed separately, are also not required to include AUC consultation information. We believe we can identify all institutional claims from a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model based on their CMS Certification Number (CCN) and allow those claims to bypass AUC program claims processing edits. We understand that when the TC and PC of advanced diagnostic imaging services are billed separately, the professional claim must identify in box 32 the location where the TC of the imaging service was furnished to the patient. Therefore, we believe we will have the ability to identify situations in which the imaging service was furnished in a hospital that is paid under the Hospital Payment Program within the Maryland Total Cost of Care Model and exclude those claims from being subject to AUC program claims processing edits. We believe this can be accomplished by using the CCN and will continue to work to determine if a list of CCNs can be used as the source of our edits in addition to determining the frequency that the list will be updated.

Note that advanced diagnostic imaging services furnished in applicable settings in the state of Maryland and paid under an applicable payment system are subject to the AUC program—the above discussion applies only to the outpatient departments of hospitals that are paid under the Hospital Payment Program within the Maryland Total Cost of Care Model.

iv. Inpatients Converted to Outpatients

While uncommon, there are situations in which a beneficiary's hospital inpatient status is changed to outpatient. Certain criteria must be met for this to occur and, if met, condition

code 44 (inpatient admission changed to outpatient) is appended to the institutional claim (*https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r299cp.pdf*). We propose to allow institutional claims with condition code 44 to bypass AUC claims processing edits. We make this proposal because, at the time advanced diagnostic imaging services were ordered and furnished, they were ordered for and furnished to a beneficiary who was in inpatient status. As such, the AUC consultation requirement would not have applied at that time. We believe that any professional claims would include place of service code 21 (inpatient hospital) since the expectation, until just prior to discharge, would be that the patient is in an inpatient status. We expect less than half of one percent of claims will include condition code 44.

v. Deny or Return Claims That Fail AUC Claims Processing Edits

As discussed above, claims that do not properly include AUC consultation information will not be paid once we fully implement the AUC claims processing edits. We are considering whether claims that do not pass the AUC claims processing edits, and therefore will not be paid, should be initially returned to the health care provider so they can be corrected and resubmitted, or should be denied so they can be appealed. On one hand, we expect there will be some errors in reporting AUC consultation information on claims, especially early on, and health care providers might find it helpful to have the opportunity to correct claims. However, there may be situations in which the health care provider would prefer the claim be denied so they have an earlier opportunity to appeal. We are requesting comments to help us better understand which path would be most appropriate once we fully implement the AUC program claims edits. Additionally, we are requesting comments on whether the payment penalty phase should begin first with returning claims and then transition to denying claims after a period of time, which may be helpful to furnishing professionals and facilities as they become more proficient in submitting claims under the AUC program.

vi. Medicare as a Secondary Payer

We understand based on feedback from stakeholders that, in some EHRs, the primary payer information is readily available and known to the ordering professional; however, secondary payer information typically is not available. Additionally, it is possible that when Medicare is the secondary payer that no Medicare payment would be made at all after the primary payer makes payment. Medicare is reported as the secondary payer for approximately 1.5 percent of advanced diagnostic imaging services that are subject to the AUC program. Because the secondary payer information for a patient generally is not available to the ordering professional, and because no Medicare payment may be involved at all when Medicare is the secondary payer, we propose to exclude claims that identify Medicare as the secondary payer from application of the AUC consultation and reporting requirements. Specifically, we propose to allow claims that identify Medicare as the secondary payer (using block 1 or the electronic equivalent of the practitioner claims and using FL 50/51 or the electronic equivalent of institutional claims) to bypass the AUC program claims processing edits.

vii. Date of Service and Date of Order

We will specify a start date for the AUC program claims processing edits to take effect. Medicare claims include a date of service but do not allow for the date of an imaging order to be recorded. Because we cannot identify the order date for an advanced imaging service based on claims, we propose that the AUC program claims processing edits for the payment penalty phase will be applicable for advanced imaging services furnished on or after the effective date of the claims edits. For imaging services ordered prior to, but furnished on or after the effective date of the AUC program claims processing edits, the furnishing professional would apply the separate HCPCS modifier discussed in section III.F.4.b.ii. (Critical Access Hospitals) of this proposed rule to indicate that the claim is not subject to the AUC claims processing edits.

viii. HCPCS Modifiers

We established two primary sets of HCPCS modifiers for this program. One set is to be included on the same claim line as the G-code identifying the CDSM that was consulted, and reports whether the imaging service adheres to the AUC (modifier ME), does not adhere to the AUC (modifier MF), or the qualified CDSM does not contain AUC that applies to the order (modifier MG). We intend for these modifiers to continue to be used when the program enters the payment penalty phase. Additionally, reporting of these modifiers should be limited to one per qualified CDSM G-code since these modifiers are mutually exclusive.

The second set of HCPCS modifiers is available for use when the ordering professional does not consult a qualified CDSM. On these claims, providers would not add a G-code for a CDSM because a consultation did not take place, and the HCPCS modifier would be included on the same line as the procedure code for the advanced diagnostic imaging service that was furnished. These HCPCS modifiers include the three that were created to describe significant hardship exceptions (insufficient internet access (modifier MB), EHR or CDSM vendor issues (modifier MC) and extreme and uncontrollable circumstances (modifier MD)). Additionally, section 1834(q)(4)(C) of the Act includes an exception for services ordered for an individual with an emergency medical condition and modifier MA is available to identify claims for patients with a suspected or confirmed emergency medical condition. This set of codes is mutually exclusive and we expect only one to be reported per procedure code-level claim line.

Modifier QQ was created for use during the voluntary period, before more detailed modifiers and codes were created, to indicate that an ordering professional consulted a qualified CDSM for the service and related data was provided to the furnishing professional. The descriptor for this code explains that the ordering professional consulted a qualified CDSM for this service and the related information was provided to the furnishing professional. Modifier QQ continues to be available for use through the educational and operations testing period, but we intend to end the use of that modifier and not carry it forward into the payment penalty phase since we have established and will require the use of distinct modifiers to communicate specific AUC consultation information.

Modifier MH was created for use during the educational and operations testing phase to identify claims for which AUC consultation information was not provided to the furnishing professional and furnishing facility. When the AUC program enters the payment penalty phase, we will no longer have a need for this modifier because claims will be required to include AUC consultation information or indicate a reason the information is not required in order to avoid AUC program claims processing edits. Beginning for services furnished on and after the effective date of the AUC program claims processing edits, we propose to redefine modifier MH to describe situations in which the

ordering professional is not required to consult AUC and the claim is not required to report AUC consultation information. For example, we would repurpose modifier MH to be used in the scenarios described in sections III.F.4.b.ii. (Critical Access Hospitals), III.F.4.b.iii (Maryland Total Cost of Care Model) if other options to identify claims are not feasible, and III.F.4.b.vii. (Date of Service and Date of Order) of this proposed rule as those scenarios would fall outside the scope of the AUC program requirements.

ix. Additional Claims Processing Information

Section 1834(q)(1)(D) of the Act specifies the applicable settings for the AUC program as a physician's office, a hospital outpatient department (including an emergency department), and ambulatory surgical center and any other provider-led outpatient setting determined appropriate by the Secretary. As discussed in the CY 2019 PFS final rule (83 FR 59690 and 59691), we added IDTFs to the definition of applicable setting at § 414.94(b) to the three applicable settings specified in statute because it is a provider-led outpatient setting in which advanced diagnostic imaging services are furnished by licensed, certified nonphysician personnel under appropriate physician supervision. To identify these settings through the Medicare claims system we evaluated type of bill and place of service codes to identify those aligned with applicable settings under the AUC program. For institutional claims, we propose to limit AUC program claims processing edits to apply only to type of bill 13x (hospital outpatient). This claim type code encompasses the hospital outpatient department and the emergency department which represent all applicable settings under the program that would bill Medicare using institutional claims. For practitioner claims, we propose to limit the edits to claims with place of service codes 11 (office), 15 (mobile unit), 19 (off campus outpatient hospital), 22 (on campus outpatient hospital), 23 (emergency room) and 24 (ASC). These place of service codes should encompass all applicable settings under the AUC program as defined at § 414.94(b). Because these type of bill and place of service codes reflect the applicable settings within which advanced diagnostic imaging services must be furnished to be subject to the AUC program requirements, we believe setting these parameters will allow us to more accurately pay claims while avoiding the need for other types of professionals and facilities to append modifiers to their claims.

x. Claims Processing Summary

We have presented above some of the scenarios that CMS and stakeholders have identified as being potentially challenging or impracticable for application of the AUC program claims processing edits for purposes of the payment penalty phase. We request feedback on whether additional scenarios require consideration and whether the proposed claims processing solutions will adequately address the issues raised. We also request feedback on areas that stakeholders believe need more education to inform our ongoing outreach and education efforts. While much of the discussion is about identifying claims that are not subject to the AUC program, we note that physicians and other practitioners, or providers submitting claims for advanced imaging services that are not subject to the AUC program can voluntarily report AUC consultation information. We intend to allow those claims to process through the system. We request commenters to provide additional information to assist us in developing edits that ensure only appropriate claims are subject to AUC claims processing edits.

c. Timing of Payment Penalties

We have previously announced in August 2020, via the CMS AUC website, that the education and operations testing period of the AUC program would be extended through 2021 and the payment penalty phase would begin in January 2022. However, given the many complexities around the scope and application of AUC program claims processing edits, we believe that notice and comment rulemaking is the most appropriate means for us to discuss the implementation and claims processing issues, the start date of the payment penalty phase, and to obtain stakeholder feedback before subsequently finalizing a course of action in the final rule. This process will help ensure that we will appropriately identify claims for denial when the payment penalty phase of the program begins. In addition, we acknowledge the circumstances of physicians and other practitioners, and providers, due to the PHE for COVID–19 and that additional time may be needed to prepare for the payment penalty phase given the challenges and practice disruptions they have experienced while responding to the PHE.

The earliest that our claims processing system can begin screening claims using the AUC program claims processing edits for the payment penalty phase is October 2022. This is because it would not be possible for us to finalize implementation and claims processing plans in this final rule (typically published on or before November 1) and make those decisions effective any earlier than the 3rd calendar quarter of 2022. Implementing the types of claims processing edits necessary for this program generally requires a long lead time. However, we note that an effective date for the claims processing edits in October 2022 may be misaligned with typical annual updates to the systems used by the health care providers that are subject to the AUC program such as EHR, CDSM or claims submission systems. Therefore, we believe the earliest practicable effective date for the AUC program claims processing edits and payment penalty phase is January 1, 2023.

While the above date takes into account technical system and programming concerns, it does not expressly take into the account the impact that the PHE for COVID–19 has had, and may yet have, on practitioners, providers and beneficiaries. Therefore, we are proposing a flexible effective date for AUC program claims processing edits and payment penalty phase to begin the later of January 1, 2023, or the January 1 that follows the declared end of the PHE for COVID–19.

We acknowledge that the AUC program has been significantly delayed. We seek public comment on this proposal for the payment penalty phase to begin, and whether we have appropriately taken into account the PHE for COVID–19 and other factors. We recognize that some practitioners and institutions have already invested in qualified CDSMs, while others have had to redirect their resources during the PHE. We seek information from the public on the state of readiness of practitioners, facilities, and EHR and CDSM vendors.

5. Summary

In summary, we are providing clarifications and proposals around the scope of the AUC program specifically pertaining to updates or modifications to orders for advanced diagnostic imaging services and the extreme and uncontrollable circumstances significant hardship exception. We are also proposing several claims processing solutions to ensure accurate identification of claims that are and are not subject to the AUC program requirements. These proposals address special circumstances related to: Services furnished by a CAH, services paid under the Maryland Total Cost of

Care Model, inpatients converted to outpatients, situations when Medicare is the secondary payer, and imaging services ordered prior to the payment penalty phase but furnished on or after the start of the payment penalty phase. We also discuss identifying the ordering professional on practitioner claims for the imaging service and request feedback on whether it is more appropriate to deny or return claims that fail AUC claims processing edits. We are also proposing to begin the AUC claims processing systems edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID–19 ends. We invite the public to submit comments on these clarifications and proposals.

We will continue to post information on our website for this program, accessible at *www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/index.html*.

G. Removal of Selected National Coverage Determinations

CMS periodically identifies and removes National Coverage Determinations (NCDs) that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. Clinical science and technology evolves and items and services that were once considered state-of-the-art or cutting edge and experimental may be established as reasonable and necessary for Medicare beneficiaries or replaced by more beneficial technologies or clinical paradigms.

In the CY 2021 PFS final rule (85 FR 84472), we established rulemaking as an appropriate vehicle for receiving public comment on removing outdated NCDs, replacing the prior subregulatory administrative process used on two occasions in 2013 and 2015. Using rulemaking under section 1871(a)(2) of the Act allows us to consider removal of several NCDs at once as compared to the public comment process established in section 1862(l) of the Act, to be used in making and reconsidering individual NCDs.

Eliminating an NCD that provides national coverage for items and services means that the item or service will no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, the initial coverage determinations for those items and services will be made by local Medicare Administrative Contractors (MACs). On the other hand, removing an NCD that bars coverage for an item or service under title XVIII (that is, national noncoverage NCD), allows MACs to cover the item or service if the MAC determines that such action is appropriate under the statute. Removing a national non-coverage NCD may permit more immediate access to technologies that may now be beneficial for some uses. As the scientific community continues to conduct research, which produces new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions.

In the CY 2021 PFS final rule, we did not establish an exclusive list of criteria that we would use for identifying and evaluating NCDs for removal. Instead, based on recommendations in public comments, and to be more flexible and nimble, we added considerations to the six factors established in 2013 to guide our decision making process. In addition to the six factors listed below, we also consider the general age of an NCD, changes in medical practice/standard of care, the pace of medical technology development since the last determination, and availability and quality of clinical evidence and information to support removal of an NCD. We would consider proposing the removal of an NCD if:

- We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an ''NCD'' as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the statute.

When we evaluate particular NCDs for removal, we take into account information gathered from stakeholders, the claims data for those items and services, and factors such as whether there may be documentation requirements within the NCD that are outdated and create a barrier to coverage. The rulemaking process provides an opportunity to consider public input before the NCD would be removed. We could decide to retain those NCDs after considering public comments.

In Table 23, we list the NCDs that we propose to remove. In addition to conducting an internal review to identify appropriate NCDs for removal, we receive removal requests from a variety of external stakeholders, such as medical specialty societies, device manufacturers, beneficiaries, physicians and providers, and other interested individuals. Additionally, sometimes topics are brought to our attention by the MAC medical directors. Also, we received comments to the NCD Removal proposal in response to the CY 2021 PFS proposed rule suggesting another seven NCDs for CMS to consider removing. After reviewing those comments and considering other available evidence and information, we are proposing to remove one of those seven NCDs in this rulemaking cycle. We have opened a national coverage analysis (NCA) using the NCD process for one and believe the other five NCDs should be retained.

We solicit comment on the two NCDs discussed in Table 23, as well as comments recommending other NCDs for CMS to consider for removal in a future rulemaking or through the NCD process.

TABLE 23: Proposed NCDs for Removal

NCD Manual Citation	Name of NCD
180.2	Enteral and Parenteral Nutritional Therapy (7/11/1984)
220.6	Positron Emission Tomography (PET) Scans (09/03/2013)

The following outlines each NCD and provides a summary of the rationale for removal. Each of the current NCDs below is available in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/*

Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.

1. NCD 180.2 Enteral and Parenteral Nutritional Therapy (July 11, 1984)

- *Circumstances/Factor:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- *Rationale:* External stakeholders suggested that portions of this NCD are outdated. Enteral nutrition is the delivery of food to a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength. Enteral nutrition is provided through a nasogastric, jejunostomy, or gastrostomy tube. Parenteral nutrition is provided intravenously to the patient with pathology of the alimentary tract severe enough, that it does not allow for absorption of sufficient nutrients. This NCD does not provide as a matter of course, for pharmacy prepared parental solutions, which would increase patient safety. It also unnecessarily adds to patient and provider burden as it requires repeated reviews of medical necessity for those individuals who need enteral or parenteral nutrition services as a result of chronic diseases that affect the ability to eat or to digest/absorb nutrition. Local contractors have proposed LCDs that, if finalized, would provide parenteral and enteral nutrition coverage for certain Medicare beneficiaries. Therefore, we believe that removing this NCD would better serve the needs of the Medicare program and its beneficiaries.

2. NCD 220.6 Positron Emission Tomography (PET) Scans (September 3, 2013)

- *Circumstances/Factor:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- *Rationale:* External stakeholders suggested this NCD may be outdated. NCD 220.6 established broad national non-coverage for non-oncologic indications of PET and was established in 2000. Thus we required that every non-oncologic indication for PET must have its own NCD in order to receive coverage. In 2013, we reconsidered the NCD to allow coverage for diagnostic PET imaging for oncologic uses not already determined by an NCD, to be made at the discretion of local Medicare administrative contractors (MACs), due to ''various improvements in the technical, regulatory and professional aspects of PET imaging for diagnosis.'' Since the 2013 reconsideration, new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents. We believe that local contractor discretion provides an immediate avenue to potential coverage in appropriate candidates for non-oncologic indications. Therefore, we are proposing to eliminate subsection 220.6 to remove the broad national bar to coverage of PET scans for non-oncologic indications, thus allowing local Medicare contractors to make a coverage determination under section 1862(a)(1)(A) of the Act for beneficiaries. We believe this framework better serves the needs of the Medicare program and its beneficiaries. For clarity, we are not proposing to change any other subsections of 220.6. Thus, the NCDs listed at 220.6.1 through 220.6.20 would not be changed by this proposal.

In summary, we solicit comment on the proposal to remove the two NCDs, as well as comments recommending other NCDs for CMS to consider for future removal. We request commenters include a rationale to support their comments. We will use the public comments to help inform our decision to take one of three actions on the three NCDs proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD by opening a National Coverage Analysis. Comments suggesting that the NCD should be revised, rather than eliminated, should include new evidence that was not previously available at the time of the original NCD or at the time the NCD was last reconsidered, in order to support a change in national coverage.

H. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

Conditions of coverage for pulmonary rehabilitation (PR), cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) are codified at 42 CFR 410.47 and 410.49. We are proposing revisions to the PR and CR/ICR regulations to emphasize that though one program treats a respiratory disease and one treats cardiac conditions, both types of programs aim to improve quality of life for their participants using similar methods. Because many components are shared between PR and CR/ICR, we strive to ensure consistency in the regulatory language used for these therapeutic programs. Additionally, we are proposing to more closely conform the PR and CR regulations by removing a PR requirement, and to add COVID–19 as a covered condition for PR for certain beneficiaries. As discussed by Fleg and colleagues (2020),[80] CR and PR continue to be severely underutilized despite clear benefits on clinical and patient-centered outcomes. In fact Million Hearts® 2022, a national initiative co-led by the Centers for Disease Control and Prevention (CDC) and CMS to prevent 1 million heart attacks and strokes within 5 years, has incorporated a goal for increasing CR utilization. Million Hearts® worked with CR professionals to set a goal of 70 percent CR participation for eligible patients.[81] With these proposals to improve accuracy and consistency of the regulatory language specifying Medicare conditions of coverage for PR and CR/ICR, we hope to assist programs to better understand the PR and CR/ICR conditions of coverage.

1. Statutory Authority

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275, July 15, 2008) (MIPPA) amended Title XVIII to add new section 1861(eee) of the Act to provide coverage of CR and ICR under Medicare part B, as well as new section 1861(fff) to provide coverage of PR under Medicare part B. The statute specified certain conditions for coverage of these services and an effective date of January 1, 2010. Conditions of coverage for PR, CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in §§ 410.47 and 410.49 respectively through the CY 2010 PFS final rule with comment period (74 FR 61872 through 61886 and 62002 through 62003 (PR) 62004 through 62005 (CR/ICR)).

2. Background

Under § 410.47(b), Medicare part B covers PR for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (COPD)

[80] Fleg J.L., Keteyian S.J., Peterson P.N., Benzo R., Finkelstein J., Forman D.E., Gaalema D.E., Cooper L.S., Punturieri A., Joseph L., Shero S., Zieman S. Increasing Use of Cardiac and Pulmonary Rehabilitation in Traditional and Community Settings: OPPORTUNITIES TO REDUCE HEALTH CARE DISPARITIES. J Cardiopulm Rehabil Prev. 2020 Nov;40 (6):350–355. doi: 10.1097/HCR.0000000000000527. PMID: 33074849; PMCID: PMC7644593.

[81] *https://millionhearts.hhs.gov/tools-protocols/action-guides/cardiac-change-package/index.html.*

(defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease and allows additional medical indications to be established through a national coverage determination (NCD). We have not expanded coverage of PR further using the NCD process.

The conditions of coverage for CR and ICR set forth in MIPPA were codified in § 410.49 through the CY 2010 PFS final rule with comment period. In 2014, we expanded coverage of CR through the NCD process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100–03) to beneficiaries with stable, chronic heart failure. Section 51004 of the Bipartisan Budget Act (Pub. L. 115–123, February 9, 2018) (BBA of 2018), amended section 1861(eee)(4)(B) of the Act to expand coverage of ICR to include patients with stable, chronic heart failure. Section 410.49 was updated to codify this expansion through the CY 2020 PFS final rule (84 FR 62897 through 62899 and 63188).

Under § 410.49(b), Medicare part B covers CR and ICR for beneficiaries who have experienced one or more of the following: (1) An acute myocardial infarction within the preceding 12 months; (2) a coronary artery bypass surgery; (3) current stable angina pectoris; (4) heart valve repair or replacement; (5) percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; (6) a heart or heart-lung transplant; (7) stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or (8) other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

As set forth in statute, PR, CR and ICR are programs furnishing physician-supervised items and services that may be furnished in a physician's office or hospital outpatient setting or in other settings determined appropriate by the Secretary.[82] When items and services are furnished under these programs, a physician must be immediately available and accessible for medical consultation and medical emergencies. PR, CR and ICR programs must include: Physician-prescribed exercise, psychosocial assessment, outcomes assessment, cardiac risk factor modification (for CR/ICR) and education or training (for PR), and individualized treatment plans (ITPs) established, reviewed and signed by a physician every 30 days. The statute also includes physician requirements for PR and CR/ICR programs. Namely, section 1861(eee)(5) of the Act requires that the Secretary establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology is responsible for the CR/ICR program and that such physician, in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program. Section 1861(fff)(3) of the Act similarly requires the Secretary establish standards that ensure that a physician with expertise in the management of individuals with respiratory pathophysiology is responsible for the PR program and, in consultation with appropriate staff, is involved substantially in directing the progress of individual in the program. We established physician standards for PR at § 410.47 and for CR/ICR at § 410.49.

Under the statute, PR and CR/ICR programs include individualized treatment that is furnished under a written plan established, reviewed, and signed by a physician every 30 days. We codified this requirement in §§ 410.47 and 410.49 by defining and describing the ITP which must be established, reviewed, and signed by a physician every 30 days. Because the statute requires a plan to be established, reviewed, and signed by a physician every 30 days, we cannot alter this requirement.

Stakeholders have indicated to us that it is very challenging for a program to fulfill these tasks on each patient's first day of PR or CR/ICR. Stakeholders have also expressed concerns that there is not separate and additional payment for medical directors or other physicians to develop and sign the ITPs. In response to these concerns, we note that the medical director and any staff physician(s) working in the PR or CR/ICR program who is involved in the patient's care and has knowledge related to the patient's condition, or the patient's treating and/or referring physician, may establish, review and sign ITPs. When appropriate and when all billing requirements are met, a separately billable evaluation and management (E/M) service may be furnished by the medical director or other PR or CR/ICR staff physician(s) working in the program in connection with establishing and signing the ITP on or before the first day of PR or CR/ICR. Additionally, physicians treating patients for their cardiovascular or respiratory conditions, but who are not staff of the PR or CR/ICR programs, are not precluded from developing and signing ITPs for their patients before they begin PR or CR/ICR programs. While the CY 2010 PFS final rule for PR (74 FR at 61883) stated that the PR physician must review and sign the ITP prior to initiation of PR even if the plan was developed by a different physician, we recognize that this imposes greater burden and may potentially delay treatment. ITPs developed and signed on or before the first day of PR by a physician who is treating the patient's respiratory condition outside of the PR program will not require an additional signature from the PR medical director (or any other physician working in the program) on or before the first day of PR. Similarly, ITPs developed and signed on or before the first day of CR/ICR by a physician outside of the CR/ICR program treating the patient's cardiovascular condition, do not require an additional signature from the CR/ICR medical director (or other physician working in the program) on or before the first day of CR/ICR. The PR and CR/ICR medical director and other appropriate staff would review these ITPs on or before the first day services are furnished. The medical director or other physician working in the program, in consultation with staff, may revise the ITP as needed to ensure the plan is appropriately individualized, regardless of which physician establishes and signs the plan.

3. Proposed Revisions

As described above, PR and CR/ICR programs are subject to many of the same statutory requirements. Despite the consistency in requirements set forth in statute, we recognize that some of the conditions of coverage codified in regulation are not identical across both programs. We are proposing conforming changes to the regulatory text for both PR and CR/ICR to establish consistency in terminology, definitions and requirements where appropriate which will result in clearer and more streamlined regulatory text. We are also proposing to adjust the regulatory structure of § 410.47 to align with § 410.49. The proposed revisions will also enable stakeholders with interest in both PR and CR/ICR programs to more easily compare requirements and implement programs.

[82] Section 51008 of the BBA of 2018 makes changes to the statute that will permit other specific practitioners to supervise the items and services effective on January 1, 2024.

a. Definitions

We are proposing revisions to six PR definitions at § 410.47(a), including individualized treatment plan, medical director, outcomes assessment, physician-prescribed exercise, psychosocial assessment and supervising physician; and revisions to three CR/ICR definitions at § 410.49(a), including medical director, outcomes assessment, and physician-prescribed exercise. Specifically, the proposed revisions to the PR definitions of ITP, psychosocial assessment and supervising physician align with the definitions of the same terms for CR/ICR. The proposed revisions to the PR definition of physician-prescribed exercise align with the definition of physician-prescribed exercise for CR/ICR and also include revisions to provide examples of physical activities appropriate to the patient population (which were relocated from the PR components section (previously § 410.47(c)). Similar revisions are proposed for the CR/ICR definition of physician-prescribed exercise. We are proposing to modify language in the PR definition of medical director to align with the CR/ICR definition of medical director to more specifically describe the role of the PR medical director. We are proposing conforming changes to the CR/ICR definition of medical director. Proposed revisions to the PR and CR/ICR definitions of outcomes assessment remove and revise redundant and unnecessary language. Also, we are proposing to clearly state that outcome assessments may be performed by either the physician or the PR or CR/ICR program staff and that all results of these evaluations performed by program staff must be considered by the physician in the development and/or review of ITPs. These proposals are consistent with descriptions provided in the CY 2010 PFS proposed rule (74 FR at 33608, 33613) which state that PR and CR/ICR staff must provide outcomes assessments to the physician and serve to clearly communicate the important supportive role program staff may play to the physicians of these rehabilitation programs. The proposed conforming changes are designed to more accurately define the existing terms and ensure consistency in definitions used for the same terms across PR and CR/ICR programs. We chose to largely maintain the CR/ICR regulatory text and align the PR regulatory text with CR/ICR based on stakeholder feedback and questions regarding the PR requirements. Aligning PR with CR/ICR, as opposed to aligning CR/ICR with PR requirements, better addresses stakeholder feedback and improves consistency in terminology, definitions and descriptions of conditions of coverage. With the proposed revisions and increased consistency, we also aim to improve program efficiency in implementing the conditions of coverage.

b. Covered Conditions

The definition for PR at § 410.47(a) specifies that PR is a physician-supervised program for COPD and certain other chronic respiratory diseases. The CDC uses the term post-COVID conditions to describe health issues that persist more than 4 weeks after first being infected with the causative virus [83] indicating that this timeframe provides a rough approximation of effects that occur beyond the acute period. Similarly, the National Institute for Health and Care Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN) and the Royal College of General Practitioners (RCGP) have jointly used 4 weeks to differentiate the acute symptoms of COVID from 'long COVID,' the signs and symptoms that continue or develop after acute COVID–19.[84] Based on the information from the CDC, NICE, SIGN and RCGP, we consider COVID–19 to be chronic when symptoms persist for more than 4 weeks. Symptoms include dyspnea, depression and anxiety which can impair physical function and cause incapacitation.[85] [86] We are proposing to cover PR for Medicare beneficiaries who have been diagnosed with severe manifestations of COVID–19, defined as requiring hospitalization in the ICU or otherwise, and who experience continuing symptomatology, including respiratory dysfunction, for at least 4 weeks post discharge.

Management of COVID–19 post-acute syndrome is an evolving issue in the health of our beneficiaries. We recognize that there is limited evidence available assessing the benefits that PR may provide for patients who were diagnosed with COVID–19. However, early research and consensus statements emphasize the restorative role that PR will likely play in the patient recovering from COVID–19.[87] [88] We are soliciting comments regarding the appropriateness of the coverage criteria for PR for beneficiaries diagnosed with COVID–19, including both the characteristics of the patients for whom PR is covered and the timing of their symptoms as presented above.

c. Components

We are proposing revisions to the description of each of the five PR components under § 410.47(b)(2) (previously § 410.47(c)). Proposed revisions to the descriptions of physician prescribed exercise, psychosocial assessment and outcomes assessment include removing language already used in the definition of each term or references to the definitions in § 410.47(a). The inclusion of already established definition language is redundant and therefore unnecessary. Proposed revisions to the education or training component more concisely explain, but do not change, the existing requirements for meeting this component. Proposed revisions to the description of the ITP align with the description used for the CR/ICR ITP. As noted in the section above, we largely align the PR regulatory text with CR/ICR to better address stakeholder feedback and improve consistency in terminology, definitions and descriptions of conditions of coverage to assist in improving program efficiency in implementing the conditions of coverage.

d. Settings

We are proposing minor edits to align the PR setting text in § 410.47(b)(3)(i) (previously § 410.47(d)(1)) with the CR/ICR setting text and reorganize this section to move and update, consistent with the corresponding CR/ICR section, the requirement that all settings must have a physician immediately available and accessible for medical consultations and emergencies.

e. Physician Standards

We are proposing revisions to align regulatory text regarding the standards for the PR medical director and the supervising physician found at

[83] Centers for Disease Control and Prevention. Post-COVID Conditions: Information for Healthcare Providers. Updated Apr. 8, 2021. Accessed 4/30/2021 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/post-covid-conditions.html.*

[84] NICE guideline [NG188]. COVID–19 rapid guideline: managing the long-term effects of COVID–19.December 18, 2020. Accessed 4/30/2021 at *https://www.nice.org.uk/guidance/ng188.*

[85] Post-COVID Conditions updated 4/8/2021 accessed 4/13/2021 at *https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects.html.*

[86] NIH launches new initiative to study ''Long COVID'' updated 2/23/21 accessed at *https://www.nih.gov/about-nih/who-we-are/nih-director/statements/nih-launches-new-initiative-study-long-covid.*

[87] Liu K., Zhang W., Yang Y., Zhang J., Li Y., Chen Y. Respiratory rehabilitation in elderly patients with COVID–19: A randomized controlled study. Complement Ther Clin Pract. 2020 May;39:101166. doi: 10.1016/j.ctcp.2020.101166. Epub 2020 Apr 1. PMID: 32379637.

[88] Barker-Davies R.M., O'Sullivan O., Senaratne KPP., et al. The Stanford Hall consensus statement for post-COVID–19 rehabilitation. Br J Sports Med. 2020;54(16):949–959. doi:10.1136/bjsports-2020–102596. PMID: 33743391.

§ 410.47(c) and (d) (previously § 410.47(e)) with the corresponding CR/ICR medical director and supervising physician text and minor conforming changes to CR/ICR language § 410.49(d) and (e). These revisions will not only align similar requirements for PR and CR/ICR programs, but also more accurately describe the roles and responsibilities of physicians in PR programs, and thereby address stakeholder feedback requesting more specificity around the roles and standards for the physicians involved in PR programs. Specifically, we are proposing to replace the existing PR ''physician standards'' section with two separate sections. The first, entitled ''medical director standards'' delineates requirements for the PR medical director, and the second, ''supervising physician standards'' delineates requirements for physicians fulfilling the supervising physician role when PR items and services are furnished. These revisions also include removing language that is redundant to the definition for medical director already set forth in § 410.47(a) and the requirement that a physician have ''direct patient contact related to the periodic review of his or her treatment plan.'' We are proposing to remove the direct patient contact language because this requirement is overly burdensome and unnecessary since a physician is already required to, in consultation with staff, review patient ITPs every 30 days. Direct physician-patient contact can be written into an ITP for patients who require such attention; however, it is not necessary for every patient and the need for it should instead be specified by the clinician. Furthermore, while we believe direct physician-patient contact within the PR program every 30 days is not necessary for every PR patient, we note that patients are seen by PR staff and their progress is tracked at each session where staff are able to identify the need for direct physician-patient contact as appropriate. Additionally, patients participating in PR generally continue to have ongoing interactions with their treating physicians outside of PR. Because the need for direct physician-patient contact is individualized and patients continue to engage with their treating physicians outside of PR, we are proposing to remove the requirement for direct physician-patient contact within the PR program every 30 days. We are requesting public comment on whether removing the regulatory requirement for direct physician-patient contact every 30 days would be potentially detrimental to PR patients by eliminating a critical physician interaction, or if necessary interactions are already occurring outside of the PR program at appropriate intervals as determined by a physician treating the patient for his or her respiratory condition.

These proposed revisions and clearer delineations of the roles and standards for the PR medical director and, separately, the supervising physician, are important to address stakeholder feedback and reduce burden on PR programs, physicians and patients while ensuring treatment is truly individualized as directed by statute. As these proposed revisions, more accurately describe and delineate the roles and standards for the medical director and the supervising physician, please note that the PR or CR/ICR medical director may serve as a supervising physician if he or she also meets the requirements for a supervising physician. Two different physicians are not necessarily required, as long as the definitions and descriptions in §§ 410.47 and 410.49 are met.

f. Limitations

We are proposing conforming changes to § 410.47(e) (previously § 410.47(f)) and § 410.49(f) to improve clarity of these sections and more closely align the descriptions for session duration, number of sessions covered and time-period over which sessions must be provided.

4. Summary

To improve consistency and accuracy across PR and CR/ICR conditions of coverage, we are proposing largely conforming changes throughout §§ 410.47 and 410.49. We are also proposing to add coverage of PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge and to remove a PR program requirement that is overly burdensome and unnecessary for all PR patients which was also not expressly required in statute. We believe these proposals result in clearer and more streamlined regulatory text and better assist stakeholders in understanding and implementing PR, CR and ICR programs. We look forward to public comments on our proposals, in particular our proposals to remove the PR direct physician-patient contact requirement and to add coverage of PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge.

I. Medical Nutrition Therapy

Medical nutrition therapy became a distinct Medicare benefit under section 1861(s)(2) of the Act pursuant to section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (BIPA). Medicare beneficiaries with diabetes or renal disease can receive individualized medical nutrition therapy (MNT) provided by a registered dietitian or nutrition professional, pursuant to a referral by a physician (as defined in section 1861(r)(1) of the Act), with no cost to the beneficiary. Currently, 42 CFR 410.132(c), further requires that the referral must be made by the treating physician. The treating physician was defined as the primary care physician or specialist, coordinating care for the beneficiary with diabetes or renal disease. The regulation also specifically defines renal disease as including chronic renal insufficiency based on glomerular filtration rate (GFR) eligibility criteria.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Kidney Foundation and Academy of Nutrition and Dietetics support MNT for adults with chronic kidney disease (CKD). The National Kidney Foundation and the Academy of Nutrition and Dietetics' Clinical Practice Guideline on Nutrition in Chronic Kidney Disease [89] acknowledges that the goals of MNT are to optimize nutritional status, and to minimize risks imposed by comorbid conditions and alterations in metabolism on the progression of kidney disease and on adverse clinical outcomes. The authors recognize that patients with CKD have changing needs according to their disease stage and they recommended MNT for each stage of CKD.

In addition, evidence supports the use of MNT as a component of quality diabetes care, including its integration into the medical management of diabetes. Nutrition therapy that includes the development of an eating plan designed to improve blood glucose, blood pressure, and lipid profiles is important in the management of diabetes and can lower the risk of cardiovascular disease, coronary heart disease, and stroke. Despite these findings and endorsement by leading clinical societies, including the American Diabetes Association, American College of Cardiology and the

[89] *https://www.kidney.org/sites/default/files/Nutrition_GL%2BSubmission_101719_Public_Review_Copy.pdf.*

National Kidney Foundation, less than 1 percent of the estimated 14 million eligible Medicare beneficiaries have accessed MNT.

Over the years, we have heard from several stakeholder groups requesting that we update the MNT regulations to improve beneficiary access. In this proposed rule, we provide background on the MNT services, discuss the MNT regulation revisions, and make proposals to implement these modifications. We are proposing to make changes to the treating physician requirements and update the chronic renal insufficiency GFR criteria in order to improve access and utilization of the MNT benefit. The statute expressly requires the order of a physician; therefore, we are unable to extend referral privileges to NPPs.

1. Background: MNT

MNT is defined in sections 1861(s)(2)(V) and 1861(vv)(1) of the Act and codified in 42 CFR 410.130 (definitions), § 410.132 (MNT), and § 410.134 (provider qualifications).

a. Definitions (§ 410.130)

In 42 CFR subpart G, we define the following definitions that apply to MNT at § 410.130:

- Chronic renal insufficiency.
- Diabetes.
- Episode of care.
- Medical nutrition therapy services.
- Physician.
- Renal disease.
- Treating physician.

b. Medical Nutrition Therapy (§ 410.132)

In § 410.132(a), we outline the conditions for coverage of MNT services. That is, Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by the treating physician. Services covered consist of face-to-face nutritional assessments and interventions in accordance with nationally-accepted dietary or nutritional protocols. The regulation contains an exception that permits MNT services to be provided as telehealth services under § 410.78.

In § 410.132(b), we outline the limitations on coverage of MNT services. First, the MNT services based on a diagnosis of renal disease as described in 42 CFR subpart G are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act. Also, a beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination (NCD) process. In years when the beneficiary is eligible for MNT and follow-up DSMT, Medicare will cover the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the NCD process. Under the current MNT NCD (NCD 180.1), Medicare covers 3 hours of MNT the initial year of referral and up to 2 hours of MNT for subsequent years. In addition, if a beneficiary has both diabetes and renal disease, Medicare will cover the maximum number of hours covered under the renal MNT benefit in one episode of care unless he or she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater. Finally, an exception to the maximum number of hours described here may be made when the treating physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

At § 410.132(c), we discuss that a referral may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in 42 CFR subpart G with documentation maintained by the referring physician in the beneficiary's medical record. We also note that referrals must be made for each episode of care and any additional assessments or interventions required by a change of diagnosis, medical condition, or treatment regimen during an episode of care.

c. Provider Qualifications (§ 410.134)

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. At § 410.134, we define registered dietitian or nutrition professional as an individual who, on or after December 22, 2000: (1) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; (2) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and (3) is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a registered dietitian by the Commission on Dietetic Registration or its successor organization. However, a dietitian or nutritionist licensed or certified in a state as of December 21, 2000 is not required to hold a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; (2) and need not complete at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional. In addition, a registered dietitian in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met these requirements.

2. Proposal for MNT Revisions

a. Removal of the Treating Physician Restriction

For CY 2022, we are proposing to revise the regulations at §§ 410.130 and 410.132. Sections 1861(s)(2)(V) and 1861(vv)(1)) of the Act define MNT services as nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional pursuant to a referral by a physician (either an M.D. or D.O.) (as defined in section 1861(r)(1) of the Act). The current regulation further provides that Medicare pays for MNT services when the beneficiary is referred for the service by the treating physician, which is defined as the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease. As discussed above in section III.I.2. of this proposed rule and codified at § 410.132(c), we required referrals only by the treating physician when the beneficiary has been diagnosed with diabetes or a renal disease, with documentation maintained by the referring physician in the beneficiary's medical record. In the CY 2002 PFS final rule (66 FR 55246, November 1, 2001), we believed the treating physician requirement was necessary to ensure coordination of care by the primary care physician or specialist for beneficiaries with chronic diseases in order to assure quality (66 FR 55277).

This relatively narrow definition, however, is now believed to have contributed to the low uptake of referrals to MNT services, although we note that few studies have examined MNT use.

We are proposing to eliminate the requirement that the referral be made by the treating physician and, consistent with the language of the statute, require MNT services to be pursuant to a referral by a physician (as defined in section 1861(r)(1) of the Act) at § 410.130 and § 410.132. It would be reasonable for any physician to refer a beneficiary to MNT. The treating physician restriction is no longer necessary to expect care to be coordinated. Care coordination between the hospital or post-acute care provider and the primary care provider is the goal and a standard of care in today's medical environment. We have worked to improve, through various efforts, the exchange of patient information between healthcare settings, and that a patient's healthcare information follows them after discharge from a hospital or post-acute care provider. Such improved transitions of care and exchange of information helps to assure that Medicare beneficiaries will continue to receive quality services. We are proposing to delete the term treating and the definition of treating physician, as there is a separate definition for physician within this provision. Therefore, we are not proposing any change to Medicare's definition of treating physician and the deletion of treating physician only applies to this provision.

b. Update the GFR Eligibility Criteria for Patients With CKD

We are proposing to revise the regulations at § 410.130. Section 1861(s)(2)(V) of the Act states that MNT services are available to beneficiaries with diabetes or a renal disease. In 2001, we established the definition of chronic renal insufficiency for the purpose of the MNT benefit using definitions from the Institute of Medicine report, ''The Role of Nutrition in Maintaining Health in the Nation's Elderly.'' [90] The definitions and staging of chronic kidney disease have evolved since the release of the report and stakeholders have noted that our definition does not reflect current medical practice. Therefore, we are proposing to update the GFR eligibility criteria so that it aligns with up to date accepted standards for CKD stage III through stage V, specifically GFR 15–59 mL/min/1.73m^2. The accepted CKD staging system separates stage III into two parts: Stage III-a; and Stage III-b. Stage III-a is GFR 45–59. The existing regulatory upper limit of 50 is mid stage III-a and does not meet the widely accepted standard of when a person is diagnosed with moderate kidney disease. The NIDDK and National Kidney Foundation's staging of CKD align with the proposed change in GFR criteria.[91] [92]

3. Proposed Regulatory Text Changes

We are proposing to make changes to the treating physician requirements and GFR eligibility criteria outlined in § § 410.130 and 410.132, consistent with statutory limitations. We propose to revise § 410.130 (definitions) and § 410.132 (MNT) by: (1) Revising the chronic renal insufficiency definition; (2) striking the treating physician definition; and (3) revising conditions for coverage of MNT services, limitations on coverage of MNT services, and referrals.

(1) Definition of Chronic Renal Insufficiency

We propose to revise § 410.130 by revising the chronic renal insufficiency definition by removing the GFR eligibility criteria of 13—50 ml/min/1.73m2 and replacing with 15—59 ml/min/1.73m2.

(2) Definition of Treating Physician

We propose to revise § 410.130 by removing the definition of treating physician.

(3) Proposed Changes to Conditions for Coverage of MNT Services, Limitations on Coverage of MNT Services, and Referrals

At § 410.132, we are proposing to revise conditions for coverage of MNT services, limitations on coverage of MNT services, and referrals by removing the terms ''the'' and ''treating,'' and replacing them with ''a,'' at paragraphs (a), (b)(5), and (c). In paragraph (c), we are also proposing to strike the term, ''maintained,'' and replace it with the term, ''noted.''

4. Summary

The MNT services may help reduce illnesses and improve quality of life for people with diabetes or renal disease. We believe the proposed changes to the treating physician requirements and GFR eligibility criteria are in the best interest of the Medicare program and its beneficiaries. The physician requirement change will increase the capacity and availability of physicians who can refer beneficiaries to MNT, which would alleviate some of the demand on primary care physicians as the usual source to perform this particular function. We note that stakeholders have contacted CMS and suggested such flexibility in the past. We recognize that MNT is not a highly utilized service and we believe these revisions will allow for Medicare patients to gain greater access to MNT services. We look forward to receiving public comment on these proposals.

J. Medicare Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.) Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (the CURES Act) (Pub. L. 114–255, December 13, 2016). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018), further

[90] IOM (2000). The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare. Retrieved from *http://www.nap.edu/catalog/9741.html.*

[91] NIH (National Institute of Diabetes and Digestive and Kidney Diseases) (2021). Kidney Disease Statistics for the United States. Retrieved from *https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease.*

[92] National Kidney Foundation (2021). eGFR. Retrieved from *https://www.kidney.org/atoz/content/gfr.*

amended section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (hereinafter referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the Public Health Emergency (PHE) for COVID–19 (85 FR 19267 and 19268).

In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8, 2020, and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS proposed rule for a summary of policies finalized in prior PFS rules (84 FR 40705). In the CY 2021 PFS final rule, we finalized new Shared Savings Program quality reporting requirements that align with the Alternative Payment Model (APM) Performance Pathway (APP) under the Quality Payment Program and revised the quality performance standard for performance years beginning on or after January 1, 2021, to reduce reporting burden and focus on patient outcomes. We also finalized a policy that waived the requirement that ACOs administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for ACOs survey for performance year 2020. In addition, we finalized updates to the definition of primary care services used

for beneficiary assignment, and policies to reduce burden associated with repayment mechanisms. In the CY 2021 PFS final rule, we also finalized the Shared Savings Program provisions included in the March 31, 2020 COVID–19 IFC and the May 8, 2020 COVID–19 IFC, with several modifications in response to public comments received.

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the statute. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program.

As a general summary, in this proposed rule, we are proposing to:

- Clarify the Application of the CAHPS for MIPS Survey sampling policies, including the CAHPS for MIPS minimum sampling thresholds, for Shared Savings Program ACOs.
- Amend the reporting requirements under the APM Performance Pathway (APP) for performance year 2022 and performance year 2023.

++ Solicit comments on addressing health disparities and promoting health equity.

++ Solicit comments on the feasibility of TIN level reporting and sampling for eCQMs/MIPS CQMs.

++ Solicit comments on reporting options for specialist providers within an ACO.

++ Update the APM Performance Pathway (APP) measure set to remove the Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions (MCC) for ACOs and replace it with the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS.

- Amend the quality performance standard for performance year 2023 by freezing the quality performance standard at the 30th percentile MIPS Quality performance category score.

++ Solicit comments on publicly displaying prior year performance scores that equate to the 30th or 40th percentile MIPS Quality performance category scores.

- Revise the extreme and uncontrollable circumstances policy to align with the proposal to freeze the quality performance standard at the 30th percentile MIPS Quality performance category score for performance year 2023.
- Update the definition of primary care services used in beneficiary assignment at § 425.400(c).
- Revise the repayment mechanism arrangement policy in the following manner:

++ To reduce the percentages used in the existing methodology for determining the repayment mechanism amount and to specify the number of assigned beneficiaries used as a multiplier in the calculations, such that the ACO's repayment mechanism amount would be calculated as the lesser of the following: (1) One-half percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures and the number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

++ To specify how we identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and the annual repayment mechanism amount recalculation.

++ To allow a one-time opportunity for certain ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to decrease the amount of their existing repayment mechanisms.

++ To revise the threshold for determining whether an increase in the repayment mechanism amount is required.

- Streamline the application process by revising requirements concerning the disclosure of prior participation in the Shared Savings Program by the ACO, ACO participants, and ACO providers/suppliers, in light of other requirements that consider an ACO's prior participation.
- Reduce the frequency and circumstances under which ACOs submit sample ACO participant agreements and executed ACO participant agreements to CMS.
- Amend the beneficiary notification requirement as it applies to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.
- Solicit comments on considerations related to the use of regional FFS expenditures in the Shared Savings Program's benchmarking methodology.

1. Quality and Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels, with a focus on outcomes. In the November 2011 final rule, we adopted a quality measure set spanning four domains: Patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). We subsequently updated the measures comprising the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

Between performance years 2017 (the first performance year under MIPS) and 2020, eligible clinicians who were participating in an ACO and who were subject to MIPS (MIPS eligible clinicians) were scored under the APM scoring standard under MIPS (81 FR 77260). These clinicians include any MIPS eligible clinicians who were participating in an ACO in a track, or payment model within a track (Track 1 and Levels A through D of the BASIC track) of the Shared Savings Program that is not an Advanced APM, as well as those MIPS eligible clinicians participating in an ACO in a track, or payment model within a track (Track 2, Level E of the BASIC track, and the ENHANCED track, or the Medicare ACO Track 1+ Model (Track 1+ Model)) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

In the CY 2021 PFS final rule, CMS finalized modifications to the Shared Savings Program quality reporting

requirements and quality performance standard for PY 2021 and subsequent performance years (85 FR 84720 through 84736). For performance year 2021 and subsequent years, ACOs are required to report quality data via the APP. In addition, CMS finalized a phase-in approach to the new Shared Savings Program quality performance standard that ACOs must achieve in order to be eligible to share in savings or avoid maximum losses. This phase-in allows for a gradual increase of the quality performance standard from a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores in performance years 2021 and 2022 to a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores in performance year 2023 and subsequent years.

b. Clarification of the Application of CAHPS for MIPS Sampling Policies to Shared Savings Program ACOs

In the CY 2021 PFS final rule (85 FR 84722), we finalized that beginning in performance year (PY) 2021, Shared Savings Program Accountable Care Organizations (ACOs) are required to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). As part of the APP, ACOs are required to administer the CAHPS for MIPS survey (85 FR 84730 through 84732).

In the CY 2021 PFS final rule, we noted, in response to public comments, that the CAHPS for MIPS survey uses the same survey instrument to assess the same patient experience domains (or Summary Survey Measures (SSMs)) as the CAHPS for ACO survey. We noted that both the CAHPS for MIPS and the CAHPS for ACOs survey use the same shortened, streamlined version of the survey that we implemented for both CAHPS for ACOs and CAHPS for MIPS in 2018, reflecting efforts by CMS to reduce the number of questions. Moreover, in 2019, the two programs used identical survey instruments.

As discussed in the CY 2021 PFS final rule, we conducted analyses to assess the impact of aligning CAHPS scoring and benchmarking using 2019 CAHPS for ACOs and CAHPS for MIPS data. The results of these analyses indicate that scoring ACOs using the MIPS methodology resulted in ACOs having a similar distribution of quality points as MIPS groups. This distribution was wider than the distribution of quality points using the ACO scoring methodology largely due to differences across the two programs in the approach to benchmarking (85 FR 84731).

In addition, we clarified that beneficiaries assigned to an ACO or MIPS group, who are eligible for the CAHPS for MIPS or CAHPS for ACOs survey, are randomly selected for inclusion in the sample. Samples are drawn at the ACO level for CAHPS for ACOs and at the TIN level for MIPS groups. Therefore, each ACO or MIPS group sample is representative of the ACO or group population.

We stated that due to the alignment of CAHPS for ACOs with CAHPS for MIPS, we will use the benchmarking and scoring methodology for CAHPS for MIPS to assess ACOs' performance on the CAHPS survey measures. We explained that a single set of benchmarks will be calculated using data from all applicable CAHPS for MIPS reporters. We score the CAHPS for MIPS survey as one quality measure, which is a different scoring approach from the Shared Savings Program quality scoring methodology, which scored the 10 CAHPS for ACOs SSMs in one patient/caregiver experience quality domain. As described in the CY 2017 Quality Payment Program final rule (81 FR 77284), each scored SSM has an individual benchmark and is scored individually and compared against the benchmark to establish the number of points earned. The CAHPS score is the average number of points across scored SSMs.

As stated in the CY 2021 PFS final rule (85 FR 84731), eligible beneficiaries assigned to an ACO or MIPS group are randomly selected to be included in the sample for the CAHPS for ACOs or CAHPS for MIPS survey. In the CY 2021 PFS final rule, we explained that the target sample size for CAHPS samples for all participating ACOs, groups, and virtual groups is 860; for ACOs, groups, and virtual groups with 860 or more survey-eligible patients, a random sample of 860 patients is drawn. We also noted that groups and virtual groups with fewer than 860 survey-eligible patients are eligible to participate in the CAHPS for MIPS if they meet the minimum sampling thresholds for CAHPS for MIPS:

- Large groups or virtual groups with 100 or more eligible clinicians: 416 eligible patients.
- Medium groups or virtual groups with 25–99 eligible clinicians: 255 eligible patients.
- Small groups or virtual groups with 2–24 eligible clinicians: 125 eligible patients.

These minimum sampling thresholds are necessary to ensure that groups have an adequate sample size to ensure that the survey responses will be representative of the care furnished by the clinicians in the group. Groups that do not have an adequate sample size would be at risk for not receiving enough survey responses to be representative of the care provided.

In the CY 2021 PFS final rule, we stated that we will continue to draw the CAHPS survey samples for Shared Savings Program ACOs administering the CAHPS for MIPS survey at the Shared Savings Program ACO level, with a target sample size of 860 going forward. Although we did not specifically state in the CY 2021 PFS final rule that the MIPS minimum sampling thresholds would also apply to ACOs participating in the Shared Savings Program, we want to clarify that they do apply for performance year 2021 and subsequent years. As explained in the CY 2021 PFS final rule, under the APP we are replacing the CAHPS for ACOs that was previously used in the Shared Savings Program with the CAHPS for MIPS. Because our intent in including the CAHPS for MIPS in the APP was to align reporting requirements under the Shared Savings Program with MIPS, we believe that the discussion surrounding the CAHPS for MIPS minimum sampling thresholds for groups and virtual groups can be reasonably understood to indicate that the CAHPS for MIPS minimum sampling thresholds would also apply to Shared Savings Program ACOs. We note that we received stakeholder feedback after the publication of the CY 2021 PFS final rule asking whether the CAHPS for MIPS minimum sampling thresholds would also apply to Shared Savings Program ACOs. From the feedback received, we determined that it was necessary to clarify that the minimum sampling threshold will apply.

As discussed previously in this section, minimum sampling thresholds are necessary to ensure that ACOs have an adequate sample size to ensure that the survey responses will be representative of the care furnished by the ACO clinicians. In addition, we do not want ACOs to be required to contract with a vendor to administer the survey if there is a high risk that the ACO will not have a sufficient sample size to generate a response rate for the survey that will be sufficient to reliably calculate a score for the CAHPS for MIPS survey. Aligning the minimum sampling thresholds for ACOs with the CAHPS for MIPS minimum sampling thresholds allows for consistency across all entities reporting the CAHPS for MIPS. Furthermore, we believe applying the CAHPS for MIPS minimum

sampling thresholds does not negatively impact Shared Savings Program ACOs because, as discussed below, only a few ACOs would potentially be impacted by these minimum sampling thresholds.

Based on the analysis of proxy data from 2020, nearly all ACOs will fall into the large size classification; that is, they will have 100 or more eligible clinicians that have assigned their billing to TINs participating in the ACO. To quantify the actual number of eligible clinicians associated with each ACO, we used the latest available reassignment and claims data from an internal file that is regularly created twice each performance year to identify the number of individual providers (NPIs) associated with each ACO's participant TINs. We conducted an analysis with proxy ACO sampling frames from 2020 and 44 ACOs fell into the medium size category of 25–99 eligible clinicians, and no ACOs were determined to have fewer than 24 eligible clinicians. Based on this analysis, we estimate that few ACOs would not be able to administer the CAHPS for MIPS due to sample size. All ACOs classified as medium-sized had more than 860 beneficiaries eligible for sampling. However, based on our analysis, one large-sized ACO would not have been able to administer the CAHPS survey for PY 2020, if we had required ACOs to administer a CAHPS for MIPS survey in performance year 2020 and these sampling rules had applied at that time because the sample size requirements would not have been met. Two additional large-sized ACOs were close to the minimum sampling threshold and would have been at risk for not being able to administer the CAHPS for MIPS survey for performance year 2020. We note that in both cases, these ACOs would have been eligible for CAHPS sampling based on their counts of assigned, quality-eligible [93] beneficiaries with 2 visits during the performance year; however, a large proportion (over 50 percent) of the beneficiaries assigned to these ACOs were residing in nursing homes and institutionalized beneficiaries are excluded from CAHPS for MIPS sampling.

Given that the minimum sampling sizes are set to ensure that groups or ACOs receive enough responses to be representative of the care their clinicians provide, we believe it is important that we should not burden ACOs that fall below the thresholds with the cost of hiring a vendor and fielding a CAHPS for MIPS survey that may not produce enough responses to calculate the CAHPS for MIPS score. Accordingly, we will inform any ACO that is at risk of falling below the minimum sampling threshold that it may not have enough beneficiaries to field a CAHPS for MIPS survey prior to the deadline for contracting with a CAHPS for MIPS survey vendor. An ACO that does not meet the minimum sampling threshold to administer the survey will not receive a score for the CAHPS for MIPS survey under the APP. When an ACO fails to meet the sampling threshold and is unable to administer the survey, the ACO's measure set will be scored accordingly, and the number of measures included in the calculation of the ACO's quality performance score will be reduced from 10 to 9 measures or from 6 to 5 measures in the APP for PY 2021. This means that the denominator used to calculate the quality score will be lower, such that an ACO that falls below the minimum threshold will not be penalized for its inability to administer a CAHPS for MIPS survey.

We seek comment on this clarification that the CAHPS for MIPS Minimum Sampling Thresholds also apply to Shared Savings Program ACOs.

In section IV.A.3.d. of this proposed rule, we discuss proposals related to the CAHPS for MIPS survey. In section IV.A.3.d, the term ''performance period'' is used to describe the time-period over which quality performance is assessed under MIPS, which is a full calendar year (January 1 through December 31) (except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures). In contrast, the Shared Savings Program uses the term ''performance year'' to describe each period for which ACOs' quality performance is assessed. For performance year 2021 and subsequent performance years, the relevant period is also the full calendar year. Therefore, while the terminology used in the Shared Savings Program and MIPS differs, the period of time for which quality performance is assessed under the APP is the same for both programs.

c. Amending the Reporting Requirements Under the APM Performance Pathway for Performance Years 2022 and 2023

In the CY 2021 PFS final rule, we finalized a change to the quality reporting requirements for purposes of the Shared Savings Program (85 FR 84720 through 84734). Effective for performance year 2021 and subsequent performance years, Shared Savings Program ACOs are required to report quality data via the APP. The quality reporting requirements under the Shared Savings Program align with the requirements that apply under the APP under the Quality Payment Program. Under this new approach, ACOs only need to report one set of quality metrics via the APP to satisfy the quality reporting requirements under both the Shared Savings Program and the MIPS. The quality measures reported via the APP for purposes of the MIPS Quality performance category will also be used to determine the quality performance of the ACO for purposes of determining eligibility for shared savings and calculating shared losses, where applicable. We refer readers to Table 40 of the CY 2021 PFS final rule (85 FR 84733) for a list of the measures included in the final APP measure set for performance year 2021.

Under the policies adopted in the CY 2021 PFS final rule:

- For performance year 2021, ACOs are required to report quality data via the APP, and can choose to actively report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs are required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.
- For performance year 2022 and subsequent performance years, ACOs are required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs are required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data. All 6 measures will be included in the calculation of the ACO's quality performance score for purposes of the Shared Savings Program.

Our initial proposal in the CY 2021 PFS proposed rule included the removal of the CMS Web Interface collection type and a requirement that ACOs report quality data via the eCQM/MIPS CQM collection type starting in PY 2021. Public comments on our proposal expressed concerns about moving ACOs away from a collection type under which they report quality data on a sample of their assigned Medicare beneficiary population to a collection type that requires ACOs to report quality data on a broader, all-payer population.

For example, we received public comments expressing concerns about the increased burden of reporting eCQM/MIPS CQM measures, as ACOs would be responsible for aggregating the data across multiple ACO participant Taxpayer Identification Numbers (TINs) and submitting this data to CMS. In

[93] Quality-eligible refers to assigned beneficiaries that were alive, enrolled in Medicare Part A and Part B for the whole performance period, were not in hospice, and did not reside outside of the United States.

addition, commenters expressed concerns about the increased cost of modifying existing electronic health record (EHR) technology, obtaining new EHR interfaces and aggregation tools, and updating performance dashboards. Also, there was concern that vendors and developers would need additional lead time to update and test systems, train staff and configure tools and measurement algorithms to aggregate data at an ACO level, in order to handle the wave of new entities reporting using eCQM/MIPS CQM measures.

In the CY 2021 PFS final rule (85 FR 84730), we noted that while the three eCQM/MIPS CQM measures are based on all payer data, we believe they are appropriate for assessing the quality of care furnished by ACOs, as required by section 1899(b)(3) of the Act. These measures focus on the management of chronic health conditions that are a high priority and have high prevalence among Medicare beneficiaries. To the extent that these conditions are also prevalent among other populations of patients that receive services from the eligible clinicians participating in an ACO, we believe it is relevant to consider the quality of care that is furnished by ACO participants across all of their patients as part of assessing the overall quality of care furnished by the ACO. We also noted that measuring care delivery to all patients is appropriate because improving care processes and practices is expected to improve care for all patients (for example, improvements to an electronic health record would be expected to improve care for all patients, not just Medicare patients). Additionally, we explained that CMS would not want ACOs participating in the Shared Savings Program to improve care for Medicare beneficiaries by reducing care quality for non-Medicare beneficiaries. Thus, looking at the overall quality of care furnished to all patients is consistent with the goal of improving care furnished by ACOs, by ensuring that care delivery is improving across all patients, rather than encouraging ACOs to focus disproportionately on improving measure performance for Medicare beneficiaries.

However, in light of the concerns raised during the public comment period for the CY 2021 PFS proposed rule, in the CY 2021 PFS final rule, we decided to extend the use of the CMS Web Interface as a collection type under the APP for performance year 2021. We believed that this additional year would allow ACOs the time needed to make the necessary changes to begin reporting quality data via eCQMs/MIPS CQMs.

Since the CY 2021 PFS final rule was issued, stakeholders have continued to express concerns about requiring ACOs to report eCQMs/MIPS CQMs via the APP, due to the cost of purchasing and implementing a system wide infrastructure to aggregate data from multiple ACO participant TINs and varying EHR systems. We note that for performance years beginning on or after January 1, 2019, ACOs are required to certify that they meet the CEHRT use requirements as specified at § 425.506(f). Specifically, ACOs in a track that:

- Does not meet the financial risk standard to be an Advanced APM must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds 50 percent; or
- Meets the financial risk standard to be an Advanced APM must certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers meets or exceeds the threshold established under § 414.1415(a)(1)(i).

We define CEHRT for purposes of the Shared Savings Program at § 425.20 and the term has the same meaning as provided under § 414.1305 for purposes of the Quality Payment Program. For 2019 and subsequent years, CEHRT is defined to mean EHR technology that meets the 2015 Edition Base EHR definition and that has been certified to the 2015 Edition health IT certification criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category and includes clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures that can be electronically accepted by CMS. Health IT certified to clinical quality measure certification criteria can help to support ACOs' efforts to meet quality measure reporting requirements.

According to a recent National Association of Accountable Care Organizations (NAACOS) survey [94] regarding the readiness of ACOs to report eCQM/MIPS CQM data, NAACOS noted that 77 percent of respondents indicated they do not have the infrastructure in place to aggregate data on behalf of their ACO participant TINs on quality performance across all payers starting in 2022. On average, an ACO has 36 ACO participant TINs and the largest Shared Savings Program ACO has 436 ACO participant TINs. The NAACOS survey also noted that almost 40 percent of ACOs have more than 15 EHR systems. Additionally, stakeholders have raised privacy and other concerns about reporting eCQMs/MIPS CQMs on all-payer populations, rather than a sample of assigned Medicare beneficiaries, as required for the CMS web interface measures. These concerns focus on perceived HIPAA Privacy Rule limitations on sharing protected health information (PHI) for non-Medicare beneficiaries with an ACO.

Furthermore, we have heard concerns from ACOs that are acting as business associates of their health care provider ACO participants regarding their ability to update their business associate agreements (BAAs) to include the PHI of patients who are not covered by Medicare. Stakeholders have indicated that current agreements may only address sharing the PHI of Medicare beneficiaries. Therefore, they have raised concerns that reporting all payer eCQMs would violate their BAAs as well as the HIPAA Privacy Rule business associate requirements at 45 CFR 164.502(a) and 164.504(e).

To report eCQMs successfully, health care providers must adhere to the requirements identified by the CMS quality program in which they intend to participate. For purposes of reporting eCQMs/MIPS CQMs under MIPS, clinicians are expressly required under § 414.1340(a) to submit data on the applicable percentage of patients that meet the measure's denominator criteria, regardless of payer. Under § 414.1380(b)(1)(i)(B)(*1*)(*iii*), failure to meet this requirement may result in the clinician receiving zero points for the measure, which may adversely impact their MIPS final score and payment adjustment. As such, we believe the disclosure of all-payer data to CMS as required by § 414.1340(a) would be permitted by the HIPAA Privacy Rule under the provision that permits disclosures of PHI as ''required by law.'' [95] Under this provision, a HIPAA covered entity, or its business associate when authorized by its BAA, may use or disclose PHI to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. We note that the HIPAA Privacy Rule minimum necessary

[94] *https://www.naacos.com/assets/docs/pdf/2021/NAACOS-QualityhandoutCCSQmeeting03222021.pdf.*

[95] See 45 CFR 164.512(a).

standard does not apply to uses or disclosures that are required by law.[96]

Furthermore, the HIPAA Privacy Rule generally permits a covered entity to disclose PHI to a business associate and to allow a business associate to create, receive, maintain, or transmit PHI on its behalf, provided that the parties have a BAA that meets the requirements of 45 CFR 164.504(e) and permits the business associate to use or disclose PHI only as permitted or required by its BAA or as required by law. The BAA must, among other things, establish the permitted and required uses and disclosures of PHI by the business associate. ACO providers and suppliers that are MIPS eligible clinicians will need to review and update any relevant BAAs as necessary to include the disclosure of all-payer data, in addition to data for Medicare beneficiaries to the ACO. We believe that ACO providers/suppliers should be able to update those agreements, in consultation with their legal counsel as necessary, to reflect the need to share data for patients covered by all payers with the ACO, in order to permit the ACO to completely and accurately report data on eCQM/MIPS CQM measures consistent with the MIPS reporting requirements.

In addition, we want to correct a statement from the CY 2021 PFS final rule (85 FR 84730). In that final rule, we provided an example of how an ACO could aggregate eCQM measure data. In this example, we stated that an ACO could, on behalf of its ACO participants, combine the results from all the ACO participant TIN QRDA 3 files, by adding numerators, denominators, etc. and create an aggregate QRDA 3 file (or other compliant file format) and submit as an ACO to CMS. However, this example did not take into account the potential for duplicate patients for a given measure across the ACO participant TINs within an ACO. It also did not take into account that two of the three eCQMs require that the most recent blood pressure or HgbA1c be captured to assess performance for those measures. Accordingly, we want to clarify that an ACO that submits eCQM quality data to CMS must de-duplicate the patient level measures data across its ACO providers/suppliers to ensure that the aggregated QRDA 3 file that is submitted to CMS incorporates only quality data that meets the intent of the measure.

Based on the feedback we received, we are convinced that ACOs and their ACO participants, Health IT vendors, and developers need additional time to prepare for reporting all-payer eCQM/MIPS CQM measures. We believe the updates we are proposing to the reporting requirements under the APP are responsive to stakeholder requests to delay the requirement that ACOs report all-payer eCQM/MIPS CQM measures, while still providing incentives for ACOs that are ready report to eCQM/MIPS CQM measures. As discussed in section IV.A.3.d.(1)(d) of this proposed rule, we are proposing to extend the CMS Web Interface as a collection type for the Quality Payment Program for PY 2022 for MIPS Groups, Virtual groups, and Shared Savings Program ACOs reporting under the APP. For PY 2023, we are proposing that the CMS Web Interface would be a collection type under the APP only for Shared Savings Program ACOs. Accordingly, we are proposing to modify the quality measure set that must be reported by Shared Savings Program ACOs under the APP, as discussed in this section and section IV.A.3.c.(2)(a) of this proposed rule.

To further address stakeholder feedback about ACOs' readiness to report all-payer measures, and in particular the concerns regarding aggregation of eCQM/MIPS CQM data across multiple ACO participant TINs using multiple different electronic health record (EHR) technology, while also providing incentives for ACOs to take the steps necessary to report all-payer measures, we are proposing that:

- *For performance year 2022:* An ACO would be required to report on either:

++ The ten CMS Web Interface measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP, or

++ The three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQM/MIPS CQM measures, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year. We believe that allowing ACOs that report eCQM/MIPS CQM measures to meet the quality performance standard if they achieve a score that is equivalent to or higher than the 30th percentile benchmark on one measure in the APP measure set would provide an incentive to ACOs to report the eCQM/MIPS CQM measures, while allowing them time to gauge their performance on the eCQM/MIPS CQM measures before full reporting of these measures is required beginning in PY 2024. If an ACO chooses this option, its performance on all three eCQM/MIPS CQM measures would be used for purposes of MIPS scoring under the APP. If an ACO decides to report both the ten CMS Web Interface measures and the three eCQM/MIPS CQM measures, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

Please note, as indicated in Tables 25 and 40, three of the CMS Web Interface measures (Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Cessation: Screening and Cessation Intervention (Quality ID# 236)) do not have benchmarks for performance year 2022, and therefore, will not be scored. However, these measures are required to be reported in order to complete the CMS Web Interface dataset. Based on the ACO's chosen reporting option, either 6 (three eCQMs/MIPS CQMs + two claims based measures + CAHPS for MIPs Survey measure) or 10 measures (seven CMS Web Interface measures + two claims based measures + CAHPS for MIPS Survey measure) will be included in the calculation of the ACO's quality performance score.

If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

- *For performance year 2023:* The ACO would be required to report on either:

++ The ten CMS Web Interface measures, at least one eCQM/MIPS CQM measure, and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP or

++ The three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQM/MIPS CQM measures, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in

[96] See 45 CFR 164.502(b)(2)(v).

the APP measure set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year. If an ACO chooses this option, its performance on all three eCQM/MIPS CQM measures would be used for purposes of MIPS scoring under the APP. If an ACO decides to report both the ten CMS Web Interface measures and the three eCQM/MIPS CQM measures, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

If an ACO does not report at least one eCQM/MIPS CQM measure in the APP measure set, the ACO would not meet the quality performance standard.

- *For performance year 2024 and subsequent performance years:* The ACO would be required to report the three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP. If an ACO does not report any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey under the APP, the ACO would not meet the quality performance standard.

Finally, for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets MIPS data completeness and case minimum requirements we are proposing that the ACO would meet the quality performance standard, if:

- For performance year 2022. The ACO reports the ten CMS Web Interface measures or the three eCQM/MIPS CQM measures and administers a CAHPS for MIPS survey under the APP.
- For performance year 2023. The ACO reports the ten CMS Web Interface measures and at least one eCQM/MIPS CQM measure or reports the three eCQM/MIPS CQM measures, and administers a CAHPS for MIPS survey under the APP.
- For performance year 2024 and subsequent performance years. The ACO reports on the three eCQM/MIPS CQM measures and administers a CAHPS for MIPS survey under the APP.

The proposed changes are summarized in Table 24. We are proposing changes to the regulation at § 425.512(a) to reflect these changes to the quality reporting requirements for performance years 2022 and 2023. We note that as part of these proposed changes, we are also proposing to update the provision at § 425.512(a)(2), which applies to new ACOs that are in the first performance year of their first agreement under the Shared Savings Program and are able to meet the quality performance standard under the Shared Savings if they completely and accurately report all required measures via the APP, to reflect the proposed changes to the quality reporting requirements for performance years 2022 and 2023.

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TABLE 24: Comparison of APP Reporting Requirements for Performance Year 2021 through 2024

	PY 2021	PY2022	PY2023	PY2024
Shared Savings Program ACO Quality Reporting requirements	ACOs are required to report the 10 measures under the CMS Web Interface **or** the 3 eCQM/MIPS CQM measures and administer the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. Based on the ACO's chosen reporting option, either 6 or 10 measures will be included in calculating the ACO's quality performance score.	Same as PY 2021	ACOs will be required to report either the 10 measures under the CMS Web Interface **or** the 3 eCQM/MIPS CQM measures. ACOs reporting the 10 CMS Web Interface measures must also report at least one of the 3 eCQM/MIPS CQM measures under the APP. ACOs will be required to field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data.	ACOs will be required to report on the 3 eCQM/MIPS CQM measures and field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. All 6 measures will be included in calculating the ACO's quality performance score.
Shared Savings Program ACO Quality Performance Standard	A quality performance score that is equivalent to or higher than the **30th** percentile across all MIPS Quality performance category scores. Quality performance standard met: ACOs are eligible to share in savings at the maximum sharing rate; ACOs in two-sided models share in losses based on their quality score or at a fixed percentage based on Track. Quality performance standard not met: ACOs are ineligible to share savings and owe the maximum amount of shared losses, if applicable.	Same as PY 2021. However, in order to encourage all payer measure reporting if the ACO reports all 3 eCQM/MIPS CQM measures under the APP, the ACO will satisfy the quality performance standard if it achieves a performance score that is equivalent to or higher than the 30th percentile on at least one measure in the APP measure set.	Same as PY 2022. However, if an ACO does not report at least one eCQM/MIPS CQM measure, the ACO will not meet the quality performance standard.	A quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores

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We seek comment on these proposed updates to the reporting requirements under the APP for performance year 2022 and subsequent years. In addition, we are seeking comment on whether we should extend the CMS Web Interface collection type for more than the 2 years proposed above. We believe the proposed 2-year extension would provide sufficient time to allow ACOs and their ACO participants to take the necessary steps to address the concerns raised by stakeholders, but are interested in hearing if stakeholders believe additional time would be needed to enable ACOs and their ACO participants to prepare for eCQM/MIPS CQM reporting.

(1) Solicitation of Comments on Addressing Health Disparities and Promoting Health Equity

We note that we continue to believe the move to eCQM/MIPS CQM measures is the appropriate next step for ACO quality measurement. For many years, ACOs have only reported on a sample of their assigned Medicare beneficiary population, as the CMS Web Interface

only requires that ACOs report on 248 consecutively ranked beneficiaries for each measure in the CMS Web Interface measure set. As we move forward with reporting under the APP and increasing the quality performance standard as described above, we believe that looking at the overall quality of care furnished to all patients is consistent with the goal of improving care furnished by ACOs by ensuring that care delivery is improving across all patients, rather than encouraging ACOs to focus disproportionately on improving measure performance for Medicare beneficiaries. We also believe that assessing Shared Savings Program ACO quality performance on a broader population can have a positive impact on the quality of care for all groups, including Medicare beneficiaries. We also expect the transition to all-payer eCQM/MIPS CQM measures will help to address health disparities and promote health equity by promoting a single standard of care across all patients receiving care from practices participating in Shared Savings Program ACOs regardless of location or racial/ethnic group. However, we are seeking comments and recommendations on how ACOs can utilize their resources to ensure that patients, regardless of racial/ethnic group, geographic location and/or income status, have access to equal care and how ACOs can improve the quality of care provided to certain communities, while addressing the disparities that currently exist in healthcare. We are also seeking comments and recommendations on how we can encourage health care providers serving vulnerable populations to participate in ACOs and other value-based care initiatives, including whether any adjustments should be made to quality measure benchmarks to take into account ACOs serving vulnerable populations.

(2) Solicitation of Comments on Feasibility of TIN Level Reporting and Sampling for eCQMs/MIPS CQMs

To assist ACOs in reporting eCQM/MIPS CQM measures and to address concerns regarding data aggregation across multiple TINs with multiple different EHR systems, we are seeking comment on allowing ACO providers/suppliers to submit eCQMs/MIPS CQM measures to CMS at the ACO participant TIN level. CMS would then calculate/aggregate the TIN level quality data to create an ACO level score. For example, CMS could calculate the average of the decile scores for each measure for each TIN within the ACO to create an aggregate measure level score for the ACO. Alternatively, CMS could calculate an ACO-level numerator for each measure (sum of performance met across TINs within the ACO) and an ACO-level denominator (sum of the met and performance not met across TINs within the ACO), then divide the two—numerator/denominator × 100—to obtain the ACO-level performance rate. We seek comment on these two potential approaches as well as any other suggested approaches to the aggregation of ACO participant TIN level quality data at the ACO level.

While we continue to believe that reporting on all-payer data is important to improve the quality of care furnished to all patients, including Medicare beneficiaries, we have heard from stakeholders that CMS should allow ACOs to report the eCQM/MIPS CQM measures for a smaller, more defined beneficiary population rather than the all-payer population, to serve as an intermediary step to reporting on all patients. Thus, while we believe that the move to all-payer measures is the next step in quality reporting, we acknowledge that the denominator of patients for a given quality measure for an ACO may be significantly higher, depending on ACO size and composition, than for MIPS groups. Therefore, we seek comment on how stakeholders would envision CMS determining an appropriate beneficiary population. For example, should ACOs report on a small sample size similar to the sample size for the CMS Web Interface? Should CMS broaden the beneficiary sample to include all assigned beneficiaries that meet the denominator for a given measure? Should CMS provide ACOs with a bigger sample size, larger than the size that has historically been used for CMS Web Interface but smaller than all the assigned beneficiaries that meet the denominator for a given measure? Or should CMS develop ACO–level eCQM/MIPS CQM measure sampling specifications? We seek comment on whether CMS should create a specific sampling methodology for ACOs, alternate sampling methodologies that could be used, as well as phase-in and tiered implementation strategies.

(3) Comment Solicitation for Reporting Options for Specialist Providers Within an ACO

We have also heard from stakeholders that the population health/primary care focused measures in the APP are not applicable for specialist providers within an ACO. In order to address measure applicability for specialist providers, we are seeking comment on allowing ACO participant TINs to report either the eCQM/MIPS CQM measures in the APP measure set at the TIN level or the applicable MIPS Value Pathways, including how APP and MIPS Value Pathway data reported at the ACO participant TIN level could be aggregated in order to assess ACO quality performance. In addition, we seek input on the role specialists play in ACOs and what specialty measures in the current eCQM or MIPS CQM measure set should be considered for inclusion in the Shared Savings Program quality measure set in future performance years. Alternatively, how could the existing APP measure set be used or modified to reinforce the role of specialists in ACO population health strategies?

(4) Updates to the APM Performance Pathway (APP) Measure Set

In section IV.A.3.(c) of this proposed rule, we are proposing to replace the Risk-Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs (MCC for ACOs measure) with the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS (MCC for MIPS measure) for performance year 2022. We are proposing to remove the MCC for ACOs measure from the APP measure set in order to reduce the potential for confusion around performance scores and feedback for MIPS eligible clinicians who might otherwise have been scored on both measures with differing results. This proposed change would continue the transition towards alignment of the quality measures reported by MIPS eligible clinicians who are not participants in APMs, such as the Shared Savings Program, and those who are, as discussed in the CY 2021 PFS final rule (85 FR 84720). For a detailed description of this proposal refer to section IV.A.3.(c) of this proposed rule.

By removing the MCC for ACOs measure and aligning the quality measure set for the Shared Savings Program with MIPS, we would have the opportunity to align quality measurement between CMS programs. In addition, given that the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure calculated as part of the APP looks at an ACO's all Medicare population rather than just the ACO's assigned beneficiary population, we believe the proposal to move to the MCC for MIPS measure would be consistent with the approach under the APP of assessing, measuring and improving quality of care across a broader population of patients. Further details on the specifications for the MCC

for MIPS measure can be found in Table A–5 in Appendix A of this proposed rule.

Please see Table 25 for the proposed APP measure set that would be reported by Shared Savings Program ACOs for PY 2022 and subsequent performance years.

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TABLE 25: Measures included in the Proposed APM Performance Pathway Measure Set[a]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

[a]We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 236) do not have benchmarks and are therefore not scored for PY 2022; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2022 & 2023 MIPS Performance years only.

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d. Shared Savings Program Quality Performance Standard

(1) Proposal To Freeze the Quality Performance Standard at the 30th Percentile of All MIPS Quality Performance Category Scores for Performance Year 2023

The quality performance standard is the minimum performance level ACOs must achieve in order to be eligible to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions. As noted above, in the CY 2021 PFS final rule we finalized a gradual phase in of the revised quality performance standard. Specifically, an ACO would meet the quality performance standard if:

- For performance years 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring; and
- For performance year 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring (85 FR 84735).

We finalized this phase-in approach to address the concerns raised by commenters about the limited time for ACOs to gain familiarity with the new quality reporting requirements under the APP and potential challenges in meeting the new quality performance standard, as well as concerns regarding the shift from a domain-based scoring approach to the original proposal to require an ACO to achieve an overall quality score equivalent to the 40th percentile across all MIPS quality performance category scores starting in PY 2021. In conjunction with the decision to phase-in the quality performance standard, we also adopted a phase-in of the reporting requirements under the APP for Shared Savings Program ACOs, as described previously.

In the CY 2021 PFS final rule, we also discussed the potential impact of the final policies on ACO quality performance. We projected that, absent an improvement in quality performance by ACOs, roughly 1-in-5 ACOs, or approximately 20 percent of ACOs, could fall below the 40th percentile MIPS Quality performance category score by performance year 2023, and would not be eligible to share in savings or would owe maximum shared losses, if applicable (85 FR 85007 through 85008). For the CY 2021 rulemaking we conducted analysis, in order to understand better how well ACOs might perform once the CMS Web Interface is no longer an available collection type. The analysis simulated ACO performance on eCQM or MIPS CQM measures, using 2018 and 2019 quality data submitted via the CMS Web Interface. Based on the analysis of the 2018 and 2019 data there were two differing estimates of the number of ACOs that would not meet the quality performance standard. The estimated percent of Shared Savings Program ACOs falling below the 40th percentile MIPS Quality performance category score was 6.5 percent based on a simulation using 2018 data and 22.9 percent based on a simulation using 2019 data.

In the CY 2021 PFS final rule, we indicated that we would continue to monitor emerging performance to determine the impact of a measured increase to the quality performance standard. We stated that we might revisit the policy in future rulemaking in order to promote an attainable standard and degree of improvement based on initial performance under the new methodology (85 FR 85008). If our proposal to extend the availability of the CMS Web Interface as a reporting mechanism under the APP is finalized, performance year 2024 would be the first year that all ACOs would be required to report all three eCQM/MIPS CQM measures and would have no option to report data via the CMS Web Interface, with data submission beginning in 2025. However, we have heard from some ACOs that they are beginning to update their systems and workflows to further develop their capacity for reporting on the eCQM/MIPS CQM measure set in performance year 2022. These ACOs are gearing up for all-payer reporting and are performing self-tests in order to understand their performance on the 3 eCQM/MIPS CQM measures. It is also important to note that some ACOs will likely report on eCQM/MIPS CQM measures beginning with the 2021 performance year. Therefore, there is an opportunity for ACOs to gain some familiarity with meeting the requirements for these measures starting in performance year 2021. Even with all of these contingencies in place and our proposals to phase-in reporting of the eCQM/MIPS CQM measures, we still recognize that transitioning to eCQM/MIPS CQM quality data reporting and aggregation may come with unforeseen data collection and/or system operational issues. Therefore, we have concluded that it would be appropriate to freeze the quality performance at the 30th percentile MIPS Quality performance category score for an additional year; and to raise the quality performance standard in conjunction with the transition to reporting of the three eCQM/MIPS CQMs measures by all ACOs in PY 2024. Although this increase in the quality performance standard to the 40th percentile would coincide with the first full year of eCQM/MIPS CQM quality reporting, we believe our proposal to extend the CMS Web Interface for an additional 2 years and to allow for a gradual phase in of reporting the three eCQMs/MIPS CQMs is responsive to stakeholder concerns related to the transition to eCQM/MIPS CQM measures and the need for data aggregation and would provide time for both ACOs and EHR vendors to put in place processes and systems, such that ACOs will be well positioned to report eCQM/MIPS CQMs by performance year 2024.

As discussed earlier in this proposed rule, as part of this gradual phase-in to full reporting of eCQMs/MIPS CQMs, we are proposing to include incentives to encourage early adoption of full eCQM/MIPS CQM reporting prior to performance year 2024. As part of the phase-in, and in order to transition ACOs to reporting all-payer eCQM/MIPS CQM measures, for performance year 2023 we would require an ACO to report at least one eCQM/MIPS CQM measure (that meets data completeness and case minimum requirements) in addition to the CMS Web Interface measures in order to meet the quality performance standard. In addition, we are also proposing for both performance year 2022 and performance year 2023 that ACOs that elect to report all three eCQM/MIPS CQM measures and meet the data completeness requirement and case minimum requirement for all three measures would meet the quality performance standard if they achieve a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

We believe that our proposal to freeze the quality performance standard at the 30th percentile for an additional year, is consistent with the requirement in the statute that CMS increase the quality performance standard overtime. There are two ways to increase the quality performance standard: (1) By increasing the threshold for the quality performance standard, and (2) by moving to all payer measure populations that ACOs are required to report for purposes of Shared Savings Program quality. In this proposed rule, we are proposing to do both by requiring that ACOs begin the transition to reporting all-payer measures before increasing the quality performance standard starting in performance year 2024.

Therefore, we propose to freeze the quality performance standard at the 30th percentile MIPS Quality performance category score for PY 2023, and to establish incentives to encourage ACOs to begin the transition to eCQM/MIPS CQM measure reporting in PY 2022 and PY 2022. This would mean that for all Shared Savings Program ACOs, CMS would designate the quality performance standard as the ACO reporting via the APP established under § 414.1367 of this chapter and for:

- Performance year 2022, if an ACO reports:

++ The 10 CMS Web Interface measures and achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ The three eCQM/MIPS CQM measures, meeting the data completeness requirement at § 414.1340 of this chapter and case minimum requirement at § 414.1380 of this chapter for all three measures, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

If the ACO does not report any of the 10 CMS Web Interface measures or any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

• Performance year 2023, if an ACO reports:

++ The 10 CMS Web Interface measures and at least one eCQM/MIPS CQM measure, and achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

++ The three eCQM/MIPS CQM measures, meeting the data completeness requirement at § 414.1340 of this chapter and case minimum requirement at § 414.1380 of this chapter for all three measures, and achieves a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

If the ACO does not report at least one eCQM/MIPS CQM, the ACO would not meet the quality performance standard.

Our proposal to extend the CMS Web Interface collection type and phase-in the reporting of the eCQMs/MIPS CQMs provides the transition time that stakeholders have requested in order to be ready to submit aggregated data on eCQMs/MIPS CQMs. We believe that the transition to the all-payer eCQM/MIPS CQM measures is the future of Shared Savings Program quality performance assessment and that ACOs are well-positioned to impact the quality of care across an all-payer population not just the Medicare population given their redesigned care processes and quality improvement activities. Ultimately, we believe that the transition time afforded ACOs by extending the availability of the CMS Web Interface as a collection type, in conjunction with the incentives to encourage early adoption of eCQM/MIPS CQM reporting, should allow ACOs to prepare for full reporting of eCQMs/MIPS CQMs as well as the incremental increase in the quality performance standard to the 40th percentile of MIPS Quality performance category score in PY 2024. Accordingly, we are proposing that for PY 2024 and all subsequent performance years, CMS would designate the quality performance standard for all Shared Savings Program ACOs, with the exception of ACOs in the first performance year of their first agreement period under the Shared Savings Program, as the ACO reporting quality data via the APP established under § 414.1367 according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We also propose to revise the regulation at § 425.512 to reflect the extended phase-in of the ACO quality performance standard.

As we explained in the CY 2021 PFS final rule, this approach to phasing in the new, higher quality performance standard is consistent with the statutory requirement in section 1899(b)(3)(C) of the Act, which requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures or both for purposes of assessing such quality of care. We believe that even though we are proposing to freeze the quality performance standard at the 30th percentile MIPS Quality performance category score for an additional year, we will still be holding ACOs to a higher standard than the previous quality standard, which merely required ACOs to achieve the 30th percentile relative to national benchmarks on one measure in each domain. We recognize the change from the CMS Web Interface collection type to the eCQM or MIPS CQM collection type, coupled with this higher quality performance standard, adds complexity for ACOs as they may need to utilize new approaches to combining data across EHR systems to allow for a new data submission type, as well as aggregating ACO participant data for submission to CMS. However, we believe that with this proposal to delay the increase in the quality performance standard, coupled with the proposal to extend the CMS Web Interface through PY2023, with incentives for e early adoption of eCQM/MIPS CQM reporting, ACOs will have ample time to prepare for the transition to full eCQM/MIPS CQM reporting in PY 2024 and the incremental increase in the quality performance standard to the 40th percentile MIPS Quality performance category score. We also believe this proposed timeline for phasing in the new quality performance requirements under the Shared Savings Program would signal to ACOs, EHR vendors, and other stakeholders that eCQM/MIPS CQM reporting is the path forward for the Shared Savings Program and clearly establish the standard that ACOs would need to achieve in order to be eligible to share in maximum savings and avoid owing the maximum shared losses, if applicable.

We also considered the possibility of extending the freeze of the Shared Savings Program quality performance standard at the 30th percentile MIPS Quality performance category score for performance year 2024. This alternative would delay the incremental increase in the quality performance standard until all ACOs have at least one year of experience in reporting data for all three eCQM/MIPS CQM measures. This delay would allow ACOs additional time to gain experience reporting on the eCQM/MIPS CQM measures and also provide CMS with more information on ACO performance on all-payer measures and the ability of ACOs to aggregate data across multiple EHR systems and multiple practices, in order to inform the quality performance standard in outlying years. However, for the reasons described previously, we believe the timeline we are proposing for phasing in the new quality reporting and quality performance requirements will provide ample time for ACOs to prepare to meet these new requirements while also satisfying the statutory requirement that we seek to improve the quality of care furnished by ACOs over time.

We seek comment on our proposal to freeze the Shared Savings Program quality performance standard at the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring for PY 2023 and to increase the quality performance standard to the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring starting in PY 2024. In addition, we seek comment on the alternative of freezing the Shared Savings Program quality performance standard at the 30th percentile across all MIPS Quality

performance category scores, excluding entities/providers eligible for facility-based scoring for PYs 2023 and 2024.

(2) Comment Solicitation on Publicly Displaying Prior Year Performance Scores That Equate to the 30th or 40th Percentile Across MIPS Quality Performance Category Scores

Stakeholders have expressed concerns regarding the lack of information on the level of quality performance that would equate to the 30th or 40th percentile MIPS Quality performance category score and that would enable an ACO to be eligible to share in savings or to avoid maximum shared losses, if applicable. These stakeholders have expressed concern that these data are not publicly available prior to the start of a performance year and that they do not believe that ACOs have a way of determining what quality score they would need to achieve to meet the quality performance standard. For a given performance year, the 30th or 40th percentile MIPS Quality performance category score is calculated based on the distribution across all MIPS Quality performance category scores, excluding entities/providers eligible for scoring for facility-based scoring, only once MIPS final scoring is complete.

Therefore, there is no information that can be provided prior to or during the performance year. However, we note that for performance year 2018 the MIPS Quality performance category score at the 30th percentile was equivalent to 83.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 93.3. For performance year 2019 the MIPS Quality performance category score at 30th percentile was equivalent to 87.9 and the MIPS Quality performance category score at the 40th percentile was equivalent to 95.7.

We seek comment on whether publicly displaying prior year performance scores that equate to the 30th or 40th MIPS Quality performance category scores would help to address ACOs' concerns regarding the lack of advance information regarding the quality performance score they must meet in order to satisfy the quality performance standard under the Shared Savings Program. We also seek comment on other ways we could address these concerns.

e. Revisions to the Extreme and Uncontrollable Circumstances Policy

In the CY 2021 PFS final rule (85 FR 84744 through 84747), we updated the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years to align with the gradual phase in of the revised quality performance standard. Specifically, we finalized that for:

- PY 2021 and PY 2022, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 30th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 30th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 30th percentile MIPS Quality performance category score.
- PY 2023, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 40th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 40th percentile MIPS Quality performance category score (85 FR 84746).

As discussed in section III.J.1.d. of this proposed rule, we are proposing to make changes to the quality performance standard for Shared Savings Program ACOs by freezing the quality performance standard at the 30th percentile for PY 2023. Therefore, we are also proposing to update the extreme and uncontrollable circumstances policy under the Shared Savings Program consistent with the proposal in section III.J.1.d. of this proposed rule. Specifically, we propose to set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during performance year 2023, including the applicable quality data reporting period for the performance year, to equal the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

For performance years 2021 and 2022, if the ACO is able to report quality data via the APP and meets the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 30th percentile MIPS Quality performance category score. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we would apply the 30th percentile MIPS Quality performance category score.

For performance year 2023, if the ACO is able to report quality data via the APP, including at least one eCQM/MIPS CQM measure, and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we would apply the 30th percentile MIPS Quality performance category score.

Similarly, we propose that for performance year 2024 and subsequent years, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, would be set equal to the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year. If the ACO is able to report quality data via the APP and meets the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score. If the ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we would apply the 40th percentile MIPS Quality performance category score. We believe these proposed updates are appropriate to align with the proposed changes to the quality performance standard in section III.J.1.d. of this proposed rule, and would also allow impacted ACOs to be

eligible to share in savings at their maximum sharing rate or to avoid maximum shared losses, if applicable. We also propose to make conforming changes to the Shared Savings Program regulations at § 425.512(b) to reflect these proposed revisions to the extreme and uncontrollable circumstances policy.

We seek comment on these proposed revisions to the extreme and uncontrollable circumstances policy.

2. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

a. Background

Section 1899(c)(1) of the Act, as amended by the CURES Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

In the June 2015 final rule (80 FR 32746 through 32748), we expanded the definition of primary care services to include two transitional care management (TCM) codes (CPT codes 99495 and 99496), and one chronic care management (CCM) code (CPT code 99490). As discussed in the final rule, the TCM codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or SNF stay. Including these codes in the definition of primary care services reflects our belief that the work of community physicians and practitioners in managing a patient's care following discharge from a hospital or nursing facility (NF) to ensure better continuity of care for these patients and help reduce avoidable readmissions is a key aspect of primary care.

In the CY 2016 PFS final rule (80 FR 71270 through 71273), we revised the definition of primary care services to exclude services billed under CPT codes 99304 through 99318, containing the place of service 31 modifier specifying that the service was furnished in a skilled nursing facility (SNF). We also revised the definition of primary care services to include claims submitted by Electing Teaching Amendment (ETA) hospitals.

In the CY 2018 PFS final rule (82 FR 53212 and 53213), we revised the definition of primary care services to include three additional CCM service codes, 99487, 99489, and G0506, and four behavioral health integration (BHI) service codes, G0502, G0503, G0504 and G0507.

We further revised the definition of primary care services in the November 2018 final rule (also referred to as the CY 2019 PFS final rule) (83 FR 59964 through 59968), by adding new codes to the definition of primary care services (CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443), and by revising how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF.

In the May 8, 2020 COVID–19 IFC (85 FR 27582 through 27586), we revised the definition of primary care services for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the COVID–19 PHE defined in § 400.200, to include the following additions specified in § 425.400(c)(2): (1) HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in); (2) CPT codes 99421, 99422 and 99423 (online digital evaluation and management service (e-visit)); and (3) CPT codes 99441, 99442, and 99443 (telephone evaluation and management services).

In the CY 2021 PFS final rule (85 FR 84786 through 84793), we finalized the additional primary care service codes adopted in the May 8, 2020 COVID–19 IFC with modifications to allow these codes to be used in determining beneficiary assignment when the assignment window (as defined at § 425.20) for a benchmark or performance year includes any months during the PHE for COVID–19 defined in § 400.200, and to apply these additional primary care service codes to all months of the assignment window, when the assignment window includes any month(s) during the PHE for COVID–19.

In the CY 2021 PFS final rule (85 FR 84748 through 84755), we expanded the definition of primary care services for purposes of determining beneficiary assignment to include: Online digital E/M CPT codes 99421, 99422, and 99423; assessment of and care planning for patients with cognitive impairment CPT code 99483; chronic care management code CPT code 99491; exclusion of advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting; remote evaluation of patient video/images HCPCS codes G2010; virtual check-in HCPCS code G2012; non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439; principal care management HCPCS codes G2064 and G2065; and psychiatric collaborative care model HCPCS code G2214. In this same final rule (85 FR 84755 through 84756), we finalized revisions to the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF.

For performance years beginning on January 1, 2021, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(v) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 96160 and 96161 (codes for administration of health risk assessment).

(2) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(3) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(4) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(5) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(6) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under § 425.400(c)(1)(v)).

(7) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(8) 99439 (code for non-complex chronic care management).

(9) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(11) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(12) 99495 and 99496 (codes for transitional care management services).

(13) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

HCPCS codes:

(1) G0402 (code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0442 (code for alcohol misuse screening service).

(4) G0443 (code for alcohol misuse counseling service).

(5) G0444 (code for annual depression screening service).

(6) G0463 (code for services furnished in Electing Teaching Amendment hospitals).

(7) G0506 (code for chronic care management).

(8) G2010 (code for the remote evaluation of patient video/images).

(9) G2012 (code for virtual check-in).

(10) G2058 (code for non-complex chronic care management).

(11) G2064 and G2065 (codes for principal care management services).

(12) G2214 (code for psychiatric collaborative care model).

b. Proposed Revisions

(1) HCPCS and CPT Codes Used in Assignment

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and make other technical changes to the definition of primary care services, for use in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years.

We propose to revise the definition of primary care services in the Shared Savings Program regulations to include the following additions: (1) Chronic Care Management (CCM) CPT code 99X21, if finalized through the CY 2022 PFS rulemaking; (2) Principal Care Management (PCM) CPT codes 99X22, 99X23, 99X24, and 99X25, if finalized through the CY 2022 PFS rulemaking; (3) Prolonged office or other outpatient evaluation and management (E/M) service HCPCS code G2212; and (4) Communication Technology-Based Service (CTBS) HCPCS code G2252, if payment for this code is made permanent through the CY 2022 PFS rulemaking. The following provides additional information about the CPT codes and HCPCS codes that we are proposing to add to the definition of primary care services used in assignment:

• *Chronic Care Management (CCM) CPT code 99X21.* For CY 2022, the American Medical Association (AMA) CPT Editorial Panel created a new CPT code that describes CCM services furnished by clinical staff under the supervision of a physician or nonphysician practitioner (NPP) who can bill E/M services, and CCM services personally furnished by a physician or NPP. Elsewhere in this proposed rule, we propose valuation of CPT code 99X21 (*Chronic care management services with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.; each additional 30 minutes by a physician or other qualified health care professional, per calendar month*).

In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, 99490, and 99491 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), CY 2018 PFS final rule (82 FR 53212 through 53213), and CY 2021 PFS final rule (85 FR 84749 through 84750 and 84754). ''Non-complex'' CCM services (CPT codes 99490 and 99491), and ''complex'' CCM services (CPT codes 99487 and 99489) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions. They differ in the amount of clinical staff service time provided, the involvement and work of the billing practitioner, and the extent of care planning performed.

The CCM services that will be furnished under the new CPT code 99X21 are similar to the CCM services that are billed under the exiting CCM codes that are included in the Shared Savings Program's current definition of primary care services, which includes CCM CPT codes 99487, 99489, 99490, 99491 and HCPCS code G0506. Because the Shared Savings Program's definition of primary care services includes other CCM CPT codes and HCPCS codes, we believe it would be appropriate to include HCPCS code 99X21, if finalized through the CY 2022 PFS rulemaking, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years.

• *Principal Care Management (PCM) services CPT Codes 99X22, 99X23, 99X24, and 99X25.* The AMA CPT Editorial Panel has created the following new CPT codes that describe PCM services furnished by clinical staff under the supervision of a physician or NPP who can bill E/M services, and PCM services personally furnished by a physician or NPP:

++ 99X22 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*).

++ 99X23 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month*).

++ 99X24 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month.*).

++ 99X25 (*Principal care management services, for a single high-risk disease, with the following required elements: One complex chronic condition expected to last at least 3 months, and which places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death; the condition requires development, monitoring, or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities; ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*).

Because the Shared Savings Program's definition of primary care services already includes the temporary HCPCS codes G2064 and G2065 that will be replaced by the permanent CPT codes 99X22 and 99X24, and CPT codes 99X23 and 99X25 represent the same services furnished for a greater length of time, we believe it would be appropriate to propose to include CPT code 99X22, 99X23, 99X24, and 99X25, if finalized through the CY 2022 PFS rulemaking, in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years. Although the temporary HCPCS codes G2064 and G2065 will be replaced by the permanent CPT codes, the Shared Savings Program will retain the temporary HCPCS codes in the definition of primary care services used for assignment, to be used in conducting beneficiary assignment for benchmark years.

• *Prolonged office or other outpatient evaluation and management (E/M) service HCPCS code G2212:* In the CY 2021 PFS final rule (85 FR 84573 through 84574), CMS finalized a new HCPCS code G2212 *(Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services) (Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes))* to be used when billing Medicare for prolonged office/outpatient evaluation and management (E/M) visits instead of CPT code 99417, starting in 2021. We stated our belief that the creation of HCPCS code G2212 will serve to resolve the potential differences between Medicare and other interpretations of CPT rules, and better address questions about the required times and what time may be counted toward the required time to report prolonged office/outpatient E/M visits (see the CY 2020 PFS final rule for a more detailed discussion of this issue, (84 FR 62849 through 62850)).

The current definition of primary care services used in the Shared Savings Program assignment methodology includes CPT codes 99205 and 99215 (codes for office or other outpatient visit for the evaluation and management of a patient). Because HCPCS code G2212 is defined as an add-on code for those office/outpatient E/M services, representing the same underlying services being furnished for a longer period of time, we believe it would be appropriate to propose to include HCPCS code G2212 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years.

• *Communication Technology-Based Service (CTBS) HCPCS code G2252:* In the CY 2021 PFS final rule (85 FR 84536), CMS established additional coding and payment for services delivered via synchronous communication technology, which can include audio-only communication on an interim basis for CY 2021. We stated our belief that establishing payment for a longer service (11–20 minutes) on an interim basis would support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. Therefore, for CY 2021, on an interim basis, we established HCPCS code G2252 *(Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion).* Elsewhere in this proposed rule, we are proposing to pay for this service on a permanent basis starting January 1, 2022.

HCPCS code G2252 is similar to G2012 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*), but allows for an extended period of medical discussion. Because G2012 is already included the definition of primary care services at § 425.400(c), we believe including G2252 in the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2022, would result in more accurate assignment of beneficiaries based on where they receive the plurality of their

primary care services. Accordingly, we propose to include HCPCS code G2252 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2022, and subsequent performance years, if payment for the code is made permanent through the CY 2022 PFS rulemaking.

We propose to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vi) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(v) with the proposed additional CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25, and HCPCS codes G2212 and G2252, if finalized through the CY 2022 PFS rulemaking, as applicable. We propose the new provision at § 425.400(c)(1)(vi) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years. Further, we propose technical modifications to the introductory text in § 425.400(c)(1)(v) to specify the applicability of this provision for determining beneficiary assignment for the performance year starting on January 1, 2021.

(2) Extending the Applicability of the Expanded Definition of Primary Care Services in Response to the COVID–19 PHE

As previously described in this section III.J.2.a. of this proposed rule, in the May 8, 2020 COVID–19 IFC (85 FR 27582 through 27586), we adopted an expanded definition of primary care services for purposes of beneficiary assignment to reflect services furnished during the COVID–19 PHE. This expanded definition was finalized with modifications in the CY 2021 PFS final rule (85 FR 84785 through 84793). According to § 425.400(c)(2), when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 PHE defined in § 400.200, in determining beneficiary assignment, we use the primary care service codes identified in § 425.400(c)(1), and additional primary care service codes as follows:

CPT codes:

(1) 99421, 99422, and 99423 (codes for online digital evaluation and management services).

(2) 99441, 99442, and 99443 (codes for telephone evaluation and management services).

HCPCS codes:

(1) G2010 (code for the remote evaluation of patient video/images).

(2) G2012 (code for virtual check-in).

These additional primary care services are applicable to all months of the assignment window, when the assignment window includes any month(s) during the COVID–19 PHE defined in § 400.200.

In the CY 2021 PFS final rule (85 FR 84748 through 84755), we updated the definition of primary care services under § 425.400(c) permanently for purposes of determining beneficiary assignment under § 425.402 for the performance year starting on January 1, 2021, and subsequent performance years, so that the following codes would not be linked to the duration of the PHE for COVID–19: (1) HCPCS code G2010 (remote evaluation of patient video/images) and HCPCS code G2012 (virtual check-in); (2) CPT codes 99421, 99422 and 99423 (online digital evaluation and management service (e-visit)).

In the CY 2021 PFS final rule, we noted that we did not consider including CPT codes 99441, 99442, and 99443 in the definition of primary care services at § 425.400(c) on a permanent basis (85 FR 84751). Telephone E/M services CPT codes 99441 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion);* 99442 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion)*; and 99443 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion)* are non-covered services when not provided during the PHE for COVID–19, as defined in § 400.200, and so could not be included in the definition of primary care services for purposes of assignment outside the context of the PHE.

In section II.D. of this proposed rule, we are proposing to revise the timeframe for services added on a temporary basis to the Medicare telehealth services list to allow additional time for stakeholders to perform an adequate analysis of those services for consideration in determining whether to include them on the Medicare telehealth services list on a permanent basis.

In order to remain consistent with Medicare FFS payment policies, we propose to revise our existing definition of primary care services for purposes of beneficiary assignment in order to include CPT codes 99441, 99442, and 99443 until they are no longer payable under the Medicare FFS payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65. We propose to specify this modification by revising § 425.400(c)(2)(i)(A)(2) to include an exception to the applicability of the expanded definition of primary care services, to extend the timeframe for use of CPT codes 99441, 99442, and 99443, and making conforming revisions to paragraphs (c)(2)(i) and (c)(2)(ii).

(3) Incorporation of Replacement Codes Into the Definition of Primary Care Services To Reflect Current Coding

In the June 2015 final rule (80 FR 32746 through 32748), we established a policy under which we make any revisions to the definition of primary care services for purposes of beneficiary assignment through the annual PFS rulemaking process. We established this policy in order to promote flexibility for the Shared Savings Program and to allow the definition of primary care services used for assignment in the Shared Savings Program to respond quickly to HCPCS/CPT coding changes made in the annual PFS rulemaking process. Accordingly, as part of the PFS rulemaking process, we periodically update the definition of primary care services used for assignment to include additional codes that we designate as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT codes or revenue codes and any subsequently modified or replacement codes.

On a routine basis, the CPT Editorial Panel may delete existing CPT codes and replace them with new CPT codes. In addition, one use of HCPCS G-codes is to identify professional healthcare procedures and services that may not have assigned CPT codes. Thus, the CPT Editorial Panel may also create new CPT

codes to replace these temporary HCPCS codes.

Currently, there may be a period of time between the issuance of a replacement code and the effective date of the final rule that incorporates the replacement code into the definition of primary care services, when the replacement code is not captured in the Shared Savings Program assignment methodology. Therefore, we are proposing to incorporate into the definition of primary care services a permanent CPT code when it directly replaces another CPT code or a temporary HCPCS code (for example, a G-code) that is already included in the definition of primary care services for purposes of determining beneficiary assignment under the Shared Savings Program. In general, we would expect to determine that a code is a direct replacement for another code based either on its having a substantially similar code description or the relevant discussion in CMS rulemaking establishing payment for the replacement code. This proposed approach would help to ensure the appropriate identification of primary care services used in the Shared Savings Program's assignment methodology by allowing for the immediate inclusion of replacement CPT codes in the determination of beneficiary assignment and lead to continuity in the assignment of beneficiaries receiving those services based on current coding. This continuity would improve predictability for ACOs, while also increasing the consistency of care coordination for their assigned beneficiaries.

We further propose that such replacement codes would be incorporated into the definition of the primary care services for purposes of determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years, when the assignment window for a benchmark or performance year (as defined in § 425.20) includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare. For ACOs under preliminary prospective assignment with retrospective reconciliation, CMS assigns beneficiaries in a preliminary manner at the beginning of a performance year and quarterly based on the most recent 12 months of data available. For final assignment for a 12-month benchmark year or performance year, the assignment window is the 12-month calendar year that corresponds to the performance year or benchmark year. Under this proposal, a replacement CPT code that becomes effective during a 12-month initial, quarterly, or final assignment window would be included in the definition of primary care services used to determine beneficiary assignment for the applicable performance year or benchmark year. For ACOs under prospective assignment, claims-based beneficiary assignment is determined prospectively at the beginning of each benchmark and performance year based on the beneficiary's use of primary care services in the most recent 12 months for which data are available, based on an offset assignment window before the start of the benchmark or performance year. Under this proposal, a replacement CPT code that becomes effective during the offset assignment window would be included in the definition of primary care services used to determine beneficiary assignment for the applicable performance year or benchmark year.

We anticipate that we would continue to undergo periodic notice and comment rulemaking, through the annual PFS rulemaking, to amend the list of CPT codes and HCPCS codes that make up the definition of primary care services used for assignment in the Shared Savings Program to codify the applicable replacement CPT codes.

As discussed in section III.J.2.b.(1) of this proposed rule, we propose to incorporate the revised definition of primary care services used for assignment in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(vi), applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2022, and subsequent performance years. As part of this revised definition, we propose to incorporate a provision in paragraph (c)(1)(vi)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified in § 425.400(c)(1)(vi)(A) or a HCPCS code specified in § 425.400(c)(1)(vi)(B), when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

We seek comment on these proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2022, and subsequent performance years. We also welcome comments on any other existing HCPCS or CPT codes, and new HCPCS or CPT codes proposed elsewhere in this proposed rule, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

3. Repayment Mechanisms

a. Background

An ACO that will participate in a two-sided model must demonstrate that it has established an adequate repayment mechanism to provide CMS assurance of its ability to repay shared losses for which the ACO may be liable upon reconciliation for each performance year. The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on repayment mechanism arrangements.[97] We established the repayment mechanism requirements through earlier rulemaking,[98] and recently modified the repayment mechanism requirements in the December 2018 final rule (83 FR 67928 through 67938) and the CY 2021 PFS final rule (85 FR 84756 through 84763).

According to § 425.204(f)(4)(ii), for a BASIC track or ENHANCED track ACO, the repayment mechanism amount must be equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. As discussed in the December 2018 final rule (83 FR 67866), this approach allows CMS to use the same sources of revenue and expenditure data during the program's annual application cycle to estimate the ACO's repayment mechanism amount and to determine the ACO's participation options according to whether the ACO is categorized as a low revenue ACO or high revenue ACO.

As specified under § 425.204(f)(4)(iii), for agreement periods beginning on or

[97] Medicare Shared Savings Program, Repayment Mechanism Arrangements, Guidance Document, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (hereinafter Repayment Mechanism Arrangements Guidance).

[98] Refer to the November 2011 final rule, 76 FR 67802, 67937 through 67940 (establishing the requirement for Track 2 ACOs). Refer to the June 2015 final rule, 80 FR 32692, 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. We require an increase in the repayment mechanism amount if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value. Under § 425.204(f)(4)(iii), an ACO cannot decrease the amount of its repayment mechanism during its agreement period as a result of changes in its composition.

As discussed in prior rulemaking, program stakeholders have continued to identify the repayment mechanism requirement as a potential barrier for some ACOs to enter into performance-based risk tracks, particularly small, physician-only and rural ACOs that may lack access to the capital that is needed to establish a repayment mechanism with a large dollar amount (see for example, 83 FR 67929).

The design of the current repayment mechanism amount calculation, which is based on a percentage of expenditures for the ACO's assigned beneficiaries or a percentage of ACO participant revenue, seeks to approximate a percentage of the ACO's maximum possible shared losses, according to the loss recoupment limits (also referred to as the loss sharing limits) applicable to ACOs under two-sided models. Comparing the calculations for determining repayment mechanism amounts to the calculations for determining the loss sharing limits indicates that repayment mechanisms cover approximately 25 percent of estimated maximum possible losses for ACOs in the BASIC track (determined by dividing 1 percent, the percentage used in the repayment mechanism amount calculation under § 425.204(f)(4)(ii)(A), by 4 percent, the percentage of the benchmark-based loss sharing limit under Level E of the BASIC track under § 425.605(d)(1)(v)(D)(2)), and 7 percent of estimated maximum possible losses for ACOs in the ENHANCED track (determined by dividing 1 percent, the percentage used in the repayment mechanism amount calculation under § 425.204(f)(4)(ii)(A), by 15 percent, the percentage of the benchmark-based loss sharing limit under the ENHANCED track under § 425.610(g)). Based on operational experience, we have found that the repayment mechanism amounts for most ACOs are much larger than needed to cover actual losses, as repayment mechanism amount calculations have been based on a percentage of an amount that approximates the ACO's loss sharing limit (which is as high as 15 percent of updated benchmark expenditures in the ENHANCED track),[99] and actual historical shared losses have been much lower than the loss sharing limit, averaging 0.96 percent of the ACO's benchmark. Some ACOs have been required to establish repayment mechanisms with amounts that are 9 times greater than their actual shared losses. Additionally, of the 35 times ACOs have owed shared losses, as determined based on reconciliation for the Shared Savings Program's first performance year concluding on December 31, 2013, through performance years (or a performance period) in 2019, only one ACO has neglected to repay CMS timely, and most ACOs chose to repay shared losses without the use of their repayment mechanism arrangements. For the one ACO that did not repay CMS, we were able to recoup more than half of the shared losses owed using the ACO's repayment mechanism, and the remaining debt was referred to the Department of Treasury for collection.

Considering this experience, which suggests there may be low risk to the Shared Savings Program by allowing lower repayment mechanism amounts, and the potential reduction in burden on ACOs by lower repayment mechanism amounts, we believe it is appropriate to modify the approach to calculating repayment mechanism amounts. We believe reducing the required amounts of repayment mechanisms may allow ACOs to use these funds to improve patient care and coordination and reduce a potential barrier to entry into performance-based risk models.

In this section of this proposed rule, we discuss four proposed policy changes regarding required repayment mechanism amounts. Under the first policy, we would modify the methodology for calculating repayment mechanism amounts to reduce the required amounts. Second, we would specify how we identify the number of assigned beneficiaries used in the repayment mechanism amount calculation and the annual repayment mechanism amount recalculation. Third, we would permit eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to reduce the amount of their existing repayment mechanisms if their recalculated repayment mechanism amount for performance year 2022 is lower than their existing repayment mechanism amount. Fourth, we would modify the threshold for determining whether an ACO is required to increase its repayment mechanism amount during its ACO's agreement period.

b. Proposed Revisions

(1) Repayment Mechanism Amount Calculations

We considered two options for modifying the calculation of repayment mechanism amounts to result in lower amounts: (1) Reducing the percentages used in the existing repayment mechanism amount calculations specified in § 425.204(f)(4)(ii); or (2) revising the methodology to use a per beneficiary dollar amount estimation methodology. In evaluating these options, we considered the potential impact on low revenue ACOs and high revenue ACOs, as defined according to § 425.20. We also considered a balance of factors, including whether to retain an approach similar to the existing methodology or to use an alternative approach that could simplify the repayment mechanism amount calculation to make it more predictable. We also considered the magnitude of potential decreases in the repayment mechanism amounts under each option. We propose the first option, to reduce the percentages used in the existing repayment mechanism amount calculations, but we are seeking comment on the second, alternative option we considered. We propose to lower the repayment mechanism

[99] The repayment mechanism amount calculations have varied over time, and the loss sharing limits are variable based on track/level. For reference:

For BASIC track or ENHANCED track ACOs, refer to the repayment mechanism amount calculation methodology specified in § 425.204(f)(4)(ii), as described in this section of this proposed rule.

Repayment mechanism amounts for ACOs participating in Track 2 and Track 3 (subsequently renamed the ENHANCED track), in agreement periods beginning on or before January 1, 2019, are calculated as 1 percent of total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for a reference year (refer to 76 FR 67978 and 67979, 80 FR 32838, and § 425.204(f)(4)(i)).

Refer to the loss recoupment limits for Levels C, D and E of the BASIC track, Track 2 and the ENHANCED track as specified in subpart G of the Shared Savings Program regulations.

Refer to the Medicare ACO Track 1+ Model Participation Agreement (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf*), specifying a bifurcated approach used to determine the estimated amount of an ACO's repayment mechanism for consistency with the bifurcated approach to determining the loss sharing limit under the Track 1+ Model.

amounts by reducing the percentages used in our current methodology, under which we calculate the repayment mechanism amount as the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. Specifically, we propose to calculate the amount as the lesser of the following: (1) One-half (0.5) percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

Under this proposal, ACOs would receive a 50 percent decrease in their repayment mechanism amounts compared to the current methodology. These amounts would offer lower repayment mechanism amounts for ACOs, while still reserving what we believe to be a reasonable amount in the event CMS uses an ACO's repayment mechanism funds to support recoupment of shared losses. Our review of data for ACOs under a two-sided model revealed that if this repayment mechanism amount calculation method were in place for PY 2021, the mean repayment mechanism savings would be $297,665 for low revenue ACOs and $2.31 million for high revenue ACOs; the minimum repayment mechanism savings would be $27,030 for low revenue ACOs and $78,106 for high revenue ACOs; and the maximum repayment mechanism savings would be $1.97 million for low revenue ACOs and $11.70 million for high revenue ACOs.

A second, alternative option we considered would be to estimate the repayment mechanism amount using a per beneficiary dollar amount that would be based on a percentage of actual historical median per capita shared losses for Shared Savings Program ACOs, multiplied by an estimate of the size of the ACO's assigned population as identified during the annual application or annual change request cycle. In considering this option, we analyzed data from the 35 instances when Shared Savings Program ACOs in two-sided models have ever incurred shared losses, defined as performance year expenditures above the ACO's benchmark by an amount equal to or greater than the ACO's minimum loss rate. Using data from actual historical shared losses, we determined median per beneficiary shared losses were $100.90 and calculated per beneficiary dollar amounts projected to cover 5 to 25 percent of shared losses for ACOs, as illustrated in Table 26.

TABLE 26: Percentage and Dollar Amounts of Median Per Beneficiary Actual Historical Shared Losses

Percentage	Dollar Amount Corresponding to Percentage of $100.90 Per Beneficiary Losses
5 percent	$5.05
7.5 percent	$7.57
10.0 percent	$10.09
12.5 percent	$12.61
15.0 percent	$15.14
17.5 percent	$17.66
20.0 percent	$20.18
22.5 percent	$22.70
25.0 percent	$25.23

Under this second, alternative option, we considered using separate per beneficiary dollar amounts, for low revenue ACOs and high revenue ACOs. We believe using two separate percentages is supported for a number of reasons. Compared to high revenue ACOs, low revenue ACOs are likely to have a lower loss sharing limit in the BASIC track (determined as a percentage of ACO participant revenue not to exceed a percentage of the ACO's updated benchmark), under which eligible low revenue ACOs may participate for up to two agreement periods. Historically, low revenue ACOs have owed shared losses less often and have had lower amounts of per beneficiary shared losses compared to high revenue ACOs. Additionally, we believe high revenue ACOs, which tend to include institutional providers and are typically larger and better capitalized, are likely better financially prepared to secure a higher amount in their repayment mechanism than low revenue ACOs, which tend to be smaller and have less capital. For low revenue ACOs, to cover 10 percent of median actual historical shared losses, rounding to the nearest $1 increment, we considered requiring a repayment mechanism amount equal to $10 per beneficiary. For high revenue ACOs, to cover 20 percent of median actual historical shared losses we considered requiring $20 per beneficiary (refer to Table 26). These amounts would offer a lower repayment mechanism amount for 99 percent of low and high revenue ACOs with existing repayment mechanisms, while still reserving what we believe to be a reasonable amount in the event CMS uses an ACO's repayment mechanism funds to support recoupment of shared losses. Our review of data for ACOs in a two-sided model revealed that if this repayment mechanism amount calculation method were in place for PY 2021,the mean repayment mechanism savings would be $410,682 for low revenue ACOs and $3.84 million for high revenue ACOs; the minimum repayment mechanism savings would be $6,513 for low revenue ACOs and $120,491 for high revenue ACOs; and the maximum repayment mechanism savings would be $3.45 million for low revenue ACOs and $19.73 million for high revenue ACOs.

We believe there are a number of advantages to the option under which we would calculate repayment

mechanism amounts using per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs. For one, low revenue ACOs would receive additional relief through lower repayment mechanism amounts, relative to high revenue ACOs, under this approach. We believe this is appropriate considering the previously described factors: The lower potential loss liability for low revenue ACOs; historically, low revenue ACOs have incurred shared losses less often and have had lower per beneficiary shared losses compared to high revenue ACOs; and low revenue ACOs tend to be less well capitalized and may face potential barriers to establishing repayment mechanisms. Second, this approach aligns with the existing repayment mechanism amount calculation methodology, which tends to require proportionally higher amounts for high revenue ACOs, that tend to have higher average total expenditures for ACO assigned beneficiaries and higher total ACO participant revenue, compared to low revenue ACOs. Third, an approach that uses a per beneficiary dollar amount would simplify the method to calculate the repayment mechanism amount, compared to the existing methodology, and may help ACOs better project repayment mechanism amounts prior to entering two-sided models, either at the point of application to a new agreement period or during the ACO's agreement period within the BASIC track's glide path as ACOs transition from a one-sided model to a two-sided model. Lastly, this approach would lower the mean repayment mechanism amount for ACOs more than the reduction that would occur under our proposal to lower the percentages used in the existing amount calculation methodology.

However, we have significant concerns with an approach that uses a per beneficiary dollar amount that is applied based on whether an ACO is determined to be a low revenue ACO or a high revenue ACO, which if unresolved outweigh the potential benefits of the approach. For one, there would be a significant repayment mechanism amount difference for ACOs near the 35 percent threshold that differentiates low revenue ACOs and high revenue ACOs, and this difference in repayment mechanism amount may not correlate to covering a significant additional increase in risk.

Second, the determination of whether an ACO is a low revenue ACO or high revenue ACO can change during the application cycle and between performance years within an agreement period. Although changes in ACO composition have the potential to affect required amounts determined under the existing repayment mechanism amount calculation methodology, we believe ACO composition changes could result in a greater magnitude of change in the repayment mechanism amount under an approach that applies a $10 per beneficiary amount for low revenue ACOs and a $20 per beneficiary amount for high revenue ACOs.

For ACOs establishing a repayment mechanism under the per beneficiary dollar amount approach, a change in revenue determination in later stages of the application cycle or change request cycle would delay calculation of an ACO's final repayment mechanism amount. In turn, this could delay when the ACO could submit finalized repayment mechanism documentation to demonstrate it meets the repayment mechanism requirement for entering a two-sided model. We are also concerned that ACOs whose revenue determinations change from low revenue to high revenue would face a substantial increase in the required repayment mechanism amount which they could find challenging to finance. However, based on our operational experience there have been relatively few cases where an ACO's revenue determination changes during the later stages of the application review period or change request cycle.

During an ACO's agreement period, a change in the ACO's revenue determination may cause significant fluctuation in an ACO's repayment mechanism amount under an approach that calculates the repayment mechanism amount using a per beneficiary dollar amount based on whether an ACO is determined to be a low revenue ACO or a high revenue ACO. Based on our operational experience, however, few ACOs entering agreement periods beginning on July 1, 2019, and in subsequent years, have experienced a change in revenue determination during their agreement period. Section 425.600(e) specifies an approach to addressing the circumstance where an ACO that entered an agreement period under Level E of the BASIC track because it was low revenue and experienced with performance-based risk Medicare ACO initiatives, becomes high revenue during its agreement period. This approach requires the ACO to take corrective action to meet the definition of low revenue ACO, or CMS takes compliance action as specified in §§ 425.216 and 425.218, which may include termination of the participation agreement. Further, in the absence of a policy to permit decreases in the repayment mechanism amount during the ACO's agreement period, ACOs that establish a repayment mechanism based on a high revenue ACO determination and are subsequently determined to be a low revenue ACO would need to maintain a relatively higher repayment mechanism amount for the duration of their 5-year agreement period.

To resolve these concerns, we considered using a single per beneficiary dollar amount for all ACOs, based on the values described in Table 26. However, we were unable to identify a single per beneficiary dollar amount that would account for historically higher per beneficiary shared losses owed by high revenue ACOs, while resulting in lower repayment mechanism amounts compared to the existing repayment mechanism calculation approach for most low revenue ACOs. Specifically, the dollar amount that would allow for relatively lower repayment mechanism amounts for all ACOs would be $8 per beneficiary, to cover 7.5 percent of median actual historical shared losses, rounding to the nearest $1 increment, which we believe is too low for high revenue ACOs. A higher per beneficiary dollar amount, such as $15, to cover 15 percent of median actual historical shared losses, rounding to the nearest $1 increment, would be relatively disadvantageous to approximately 20 percent of low revenue ACOs.

Both our proposal and the second, alternative option would lower repayment mechanism amounts and would reduce the amount available to CMS to support repayment of shared losses. However, we believe this risk to CMS is mitigated for a number of reasons. As noted previously in this section of this proposed rule, in our analysis of repayment mechanism amounts compared to actual historical shared losses, we believe the lower amounts would continue to provide CMS with reasonable assurance of an ACO's ability to repay shared losses. Further, as discussed in earlier rulemaking (85 FR 50249), the Shared Savings Program's existing policies require ACOs to pay shared losses, in full, within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window to remain in compliance with the Shared Savings Program's requirements and avoid compliance actions including involuntary termination from the program. CMS may terminate an ACO's participation agreement for reasons

including, but not limited to, non-compliance with requirements in 42 CFR part 425 (§ 425.218(b)(1)), such as failure to repay shared losses owed according to the program's regulations and may take pre-termination actions as described in § 425.216(a). Under § 425.221(b)(2)(ii)(B), an ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. ACOs must also timely repay shared losses owed to avoid accruing interest on any unpaid amounts and to avoid referral of an unpaid debt to the Department of Treasury for collection. Based on our operational experience, nearly all ACOs fully repay shared losses without use of their repayment mechanism arrangement. ACOs will continue to have the option to secure a repayment mechanism at an amount greater than the CMS required amount, if they feel that is appropriate to prepare their ACO to repay all shared losses.

Furthermore, we believe that reduced repayment mechanism amounts could reduce costs for ACOs in fees charged by financial institutions for letters of credit and by insurance companies for surety bonds, although we would not anticipate a significant reduction in fees charged by banks or credit unions for establishing and maintaining escrow accounts. For example, reducing the required repayment mechanism amount of a given ACO by $1 million, could reduce the cost of obtaining a letter of credit or surety bond by roughly 1 or 2 percent, in this example resulting from $10,000 or $20,000 in reduced fees for the ACO. We estimate that such relief, in total for all participating ACOs, could be worth $2 to $4 million annually under the proposed approach (assuming a reduction of approximately $196 million in repayment mechanism amounts, in aggregate) and $3 to $6 million annually under the second, alternative option (assuming a reduction of approximately $322 million in repayment mechanism amounts, in aggregate).

In light of these considerations, we propose to revise the regulations in § 425.204(f)(4)(ii) to reduce by one-half the percentages used in the methodology for calculating repayment mechanism amounts for ACOs in a two-sided model of the BASIC track or the ENHANCED track. We propose to revise the percentage specified in § 425.204(f)(4)(ii)(A), for calculating an amount based on expenditures for the ACO's assigned beneficiaries, from 1 percent to one-half percent. We propose to revise the percentage specified in § 425.204(f)(4)(ii)(B), for calculating an amount based on ACO participant revenue, from 2 percent to 1 percent. Under this proposed approach for calculating repayment mechanism amounts for ACOs in a two-sided model of the BASIC track or the ENHANCED track, the repayment mechanism amount would be equal to the lesser of the following: (1) One-half percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 1 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

We seek comment on this proposal and the second, alternative option for calculating repayment mechanism amounts using a per beneficiary dollar amount, based on a percentage of actual historical median per capita shared losses for Shared Savings Program ACOs, multiplied by an estimate of the size of the ACO's assigned population as identified during the annual application or annual change request cycle. We seek comment on applying different per beneficiary dollar amounts for low revenue ACOs and high revenue ACOs under this alternative approach. We welcome comments to address the dollar amounts projected to cover the percentage of median actual historical shared losses that would be an appropriate basis for low revenue ACOs (such as $10) and high revenue ACOs (such as $20) under this methodology. We also seek comment on approaches for addressing our concerns about changes in revenue determinations significantly affecting an ACO's repayment mechanism amount, such as applying a single per beneficiary dollar amount to all ACOs. We also note that if we were to adopt such an approach, we would need to address with greater specificity factors including: (1) How we would identify the population of assigned beneficiaries that would be used in the calculation as a multiplier for the per beneficiary dollar amount; and (2) the frequency with which we would consider modifications to the per beneficiary dollar amount. We welcome comments on these considerations.

We propose that these modifications would be effective and applicable on January 1, 2022. We note that the Shared Savings Program's application cycle (for new, renewing and re-entering ACOs) and change request cycle (for ACOs within an agreement period) for the performance year beginning on January 1, 2022 occurs between spring and fall 2021. During this timeframe, ACOs preparing to enter two-sided models for performance year 2022 are awaiting the final repayment mechanism amount for establishing a repayment mechanism, and ACOs within two-sided models are awaiting the determination of whether their repayment mechanism amount must be increased in accordance with § 425.204(f)(4)(iii) (as discussed in section III.J.3.b.(4) of this proposed rule). If the proposed modifications to the repayment mechanism amount calculation methodology described in this section of this proposed rule are finalized, and effective and applicable on January 1, 2022, we would communicate to ACOs their final repayment mechanism amounts after the issuance of the final rule. We are committed to ensuring that ACOs do not overfund their repayment mechanism arrangements according to the existing methodology if we finalize the proposed revisions to reduce repayment mechanism amounts.

(2) Population of Assigned Beneficiaries Used in Calculating and Recalculating Repayment Mechanism Amounts

We propose to amend the regulations at §§ 425.204(f)(4)(ii) and 425.204(f)(4)(iii) to specify how we identify the number of assigned beneficiaries used in calculating and recalculating the repayment mechanism amount (respectively). For context, we first describe our current approach for calculating repayment mechanism amounts under § 425.204(f)(4)(ii) (for ACOs establishing a repayment mechanism to support their participation under a two-sided model) and under § 425.204(f)(4)(iii) (the annual recalculation to determine if an ACO is required to increase the amount of its repayment mechanism).

In accordance with § 425.204(f)(4)(ii), for ACOs in a two-sided model of the BASIC track, or the ENHANCED track, the repayment mechanism amount must be equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available (hereinafter referred to as an expenditure-based amount); or (2) 2 percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available (hereinafter referred to as a revenue-based amount).

Currently, we use the following steps to calculate the expenditure-based amount specified in § 425.204(f)(4)(ii)(A), which is a percentage of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available (referred to below as the ''relevant historical calendar year''):

- *Step 1:* Identify the beneficiaries that would have been assigned to the ACO for the relevant historical calendar year (determined based on the ACO participant list for the upcoming performance year submitted by the ACO for CMS' review during the application cycle or change request cycle, referred to below as the ''ACO participant list for the upcoming performance year'') and multiply the number of such beneficiaries by an assignment growth factor to account for expected growth in assignment.
- *Step 2:* Determine estimated per capita FFS expenditures by calculating the total per capita Medicare Parts A and B FFS expenditures incurred during the relevant historical calendar year by the beneficiaries identified in step 1, and dividing that amount by the total number of beneficiaries identified in step 1 before the assignment growth factor is applied; and multiplying the resulting per capita FFS expenditure amount by a dollar trend factor to account for expected growth in Medicare FFS expenditures.
- *Step 3:* Calculate the product of the number of assigned beneficiaries determined according to step 1, and the estimated per capita FFS expenditures determined according to step 2.
- *Step 4:* Calculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage (currently 1 percent).

We currently use the following steps in calculating the revenue-based amount specified in § 425.204(f)(4)(ii)(B), which is based on revenue for the most recent calendar year for which 12 months of data are available (referred to below as the ''relevant historical calendar year''):

- *Step 1:* Identify the beneficiaries that would have been assigned to the ACO for the relevant historical calendar year (determined based on the ACO participant list for the upcoming performance year) and multiply the number of such beneficiaries by an assignment growth factor.
- *Step 2:* Using the ACO participant list for the upcoming performance year, determine the estimated per capita FFS revenues of ACO participants by calculating ACO participants' total Medicare Parts A and B FFS revenue based on claims for services furnished to any beneficiary by ACO participants during the relevant historical calendar year, and dividing the dollar amount by the total number of assigned beneficiaries identified in step 1 before the assignment growth factor is applied; [100] and multiplying the resulting number by a dollar trend factor to account for expected growth in Medicare FFS revenue.
- *Step 3:* Calculate the product of the number of assigned beneficiaries determined according to step 1, and the estimated per capita FFS revenues of ACO participants determined according to step 2.
- *Step 4:* Calculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage (currently 2 percent).

Regardless of the ACO's selected assignment methodology, within step 1 of the expenditure-based and revenue-based repayment mechanism amount calculations, CMS uses an assigned beneficiary population identified based on preliminary prospective assignment with retrospective reconciliation as described in § 425.400(a)(2). This ensures that the assignment window used to determine assigned beneficiaries aligns with the relevant historical calendar year used to calculate expenditures and revenue used in step 2 of the expenditure-based amount and revenue-based amount calculation.

We believe there are several important reasons for using historical data for determining the assigned beneficiary population, Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, and ACO participants' Medicare Parts A and B FFS revenue. For one, this approach ensures CMS' timely determination of final repayment amount estimates for ACOs required to establish a repayment mechanism arrangement prior to the start of a new agreement period under a two-sided model, or prior to start of the upcoming performance year under a two-sided model (for ACOs transitioning from a one-sided to a two-sided model along the BASIC track's glide path). Second, under this approach, the data used to determine repayment mechanism amounts is consistent with the data used in making other determinations during the application cycle and annual change request cycle, including determination of whether an ACO is categorized as a low revenue ACO or high revenue ACO.

In accordance with § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period in accordance with § 425.204(f), based on the certified ACO participant list for the relevant performance year. Currently, in recalculating ACOs' repayment mechanism amounts we use the same approach to calculating the expenditure-based amount and revenue-based amount in accordance with § 425.204(f)(4)(ii), as previously described in this section. That is, in recalculating the repayment amount we determine the assigned beneficiary population, Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, and ACO participants' Medicare Parts A and B FFS revenue, for the most recent calendar year for which 12 months of data are available.

We propose to modify the methodology for the annual repayment mechanism amount recalculation. Specifically, we propose to determine the number of assigned beneficiaries that is used as a multiplier in step 3 of the expenditure-based amount and revenue-based amount calculations, based on more recently available assignment data, rather than using a population projected to be assigned to the ACO based on historical data (that is, for the most recent calendar year for which 12 months of data are available). In determining the number of beneficiaries used as a multiplier in the recalculation estimate, we propose to determine the size of the ACO's assigned population based on the number of beneficiaries assigned to the ACO at the beginning of the performance year, as specified under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or paragraph (a)(3)(i) (for ACOs under prospective assignment). This population of assigned beneficiaries is specified in the ACO's initial assignment list report for the performance year. For all ACOs, this population is identified based on an assignment window that is offset from the calendar year (that is, from October 1 through September 30 prior to the start of the performance year), and which is the basis for determining prospective assignment for the performance year. Under the proposed approach that uses more recent

[100] We divide the total Medicare Parts A and B FFS revenue by the number of assigned beneficiaries determined in step 1, as opposed to the number of beneficiaries that is the basis for determining FFS revenues in step 2, in order for the expenditure-based and revenue-based per capita amounts to be calculated on the same basis.

assignment data in determining the recalculation estimate, we would not apply an assignment growth factor as a multiplier for the population size since we would no longer be using historical data to project the size of the ACO's assigned population. We believe this proposed approach would help ensure the recalculated repayment mechanism amounts account for an ACO's composition as reflected in the size of its assigned population for the performance year for which the recalculated amount relates, and thereby provide more accurate recalculated amounts.

Under this proposed approach, we anticipate performing the annual recalculation of the repayment mechanism amounts shortly before or shortly after the start of the new performance year. CMS will perform the recalculation of the repayment mechanism once the initial assignment list report is available, which is typically delivered to ACOs in the early winter (around mid-December), prior to the start of the relevant future performance year. We also note that under the existing approach and the proposed approach to determining the assigned population used as a multiplier in the annual recalculation of the repayment mechanism amounts, the effects on ACO's amounts are varied, resulting in relatively higher or lower amounts depending on the change in the size of the population.

In annually recalculating the repayment mechanism amount under this proposed approach, we would follow the previously described steps for calculating the expenditure-based amount and revenue-based amount, with the exception of the number of beneficiaries used as a multiplier in step 3 of the calculations. In step 3 of the expenditure-based amount calculation, we would calculate the product of the total number of assigned beneficiaries specified in the ACO's initial assignment list report for the relevant future performance year, and the estimated per capita FFS expenditures determined for the relevant historical calendar year (determined according to step 2). In step 3 of the revenue-based amount calculation, we would calculate the product of the total number of assigned beneficiaries specified within the ACO's initial assignment list report for the relevant future performance year, and the estimated per capita FFS revenues of ACO participants determined for the relevant historical calendar year (determined according to step 2).

Several examples illustrate the calculation and recalculation of the repayment mechanism amounts under the proposals. First, for an ACO applying to enter a two-sided model for an agreement period beginning on January 1, 2022, we will calculate the repayment mechanism amount during the application cycle which occurs during CY 2021. During this time, CY 2020 is the most recent calendar year for which 12 months of data are available, and is the relevant historical calendar year for purposes of calculating the repayment mechanism amount. As described in this illustration, the proposed approach to identifying the assigned beneficiary population, Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, and ACO participants' Medicare Parts A and B FFS revenue used within these calculations is consistent with our current operational approach.

In step 1 of the expenditure-based amount and revenue-based amount calculations, we would identify the beneficiaries that would have been assigned to the ACO for CY 2020, determined based on the ACO participant list for PY 2022 submitted with the ACO's application, and determined using preliminary prospective assignment with retrospective reconciliation. That is, we would determine assignment based on the 12-month assignment window from January 1, 2020, through December 31, 2020.[101] We would multiply the number of such beneficiaries by an assignment growth factor.

In step 2 of the expenditure-based amount calculation, we would calculate total Medicare Parts A and B FFS expenditures incurred in CY 2020 by the beneficiaries determined under step 1 to be assigned to the ACO for CY 2020. In step 2 of the revenue-based amount calculation, we would calculate ACO participants' total Medicare Parts A and B FFS revenue, based on claims for services furnished to any beneficiary by ACO participants during CY 2020. We would determine the estimated per capita FFS expenditures, and the estimated per capita FFS revenues of ACO participants, by dividing the CY 2020 dollar amounts by the number of assigned beneficiaries for CY 2020 (determined in accordance with step 1) before the assignment growth factor is applied. We would multiply the resulting numbers by a dollar trend factor.

In step 3 of the expenditure-based amount calculation, the number of assigned beneficiaries for CY 2020 would be multiplied by the estimated per capita FFS expenditures determined for CY 2020 in accordance with step 2. In step 3 of the revenue-based amount calculation, the number of assigned beneficiaries for CY 2020 would be multiplied by the estimated per capita Medicare FFS revenues of ACO participants determined for CY 2020 in accordance with step 2.

In step 4, we would calculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage. Currently, that is 1 percent under the expenditure-based amount calculation, and 2 percent under the revenue-based amount calculation. Under the proposals described in section III.J.3.b.(1) of this proposed rule, the applicable percentages would be one-half percent under the expenditure-based amount calculation, and 1 percent under the revenue-based amount calculation.

Our second example illustrates how we would perform the annual recalculation of the repayment mechanism amount for performance year (PY) 2022.

In step 1 of both the expenditure-based amount and revenue-based amount calculations, we use a similar method for identifying the CY 2020 assigned population as described in the first example. That is, we would identify the beneficiaries that would have been assigned to the ACO for CY 2020, determined based on the ACO's certified ACO participant list for PY 2022, and determined using preliminary prospective assignment with retrospective reconciliation. Again, we would determine assignment based on the 12-month assignment window from January 1, 2020, through December 31, 2020.

In step 2 of the expenditure-based amount calculation, we would calculate total Medicare Parts A and B FFS expenditures incurred in CY 2020 by the beneficiaries determined under step 1 to be assigned to the ACO for CY 2020. In step 2 of the revenue-based amount calculation, we would calculate ACO participants' total Medicare Parts A and B FFS revenue, based on claims for services furnished to any beneficiary by ACO participants during CY 2020, using the ACO's certified ACO participant list for PY 2022. We would determine the estimated per capita FFS expenditures, and the estimated per capita FFS revenues of ACO participants, by

[101] Refer to the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #9, February 2021), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-0.*

dividing the CY 2020 dollar amounts by the number of assigned beneficiaries for CY 2020 (determined in accordance with step 1).

In step 3, we would identify the total number of assigned beneficiaries specified within the ACO's initial assignment list report for PY 2022. This population of assigned beneficiaries would be specified in the ACO's initial assignment list report for PY 2022, and would be the population identified based on the assignment window from October 1, 2019 through September 30, 2020, and which would be the basis for determining prospective assignment for PY 2022. Assignment would be determined based on the ACO's certified ACO participant list for PY 2022. In step 3 of the expenditure-based amount calculation, the number of assigned beneficiaries for PY 2022 would be multiplied by the estimated per capita FFS expenditures determined for CY 2020 in accordance with step 2. In step 3 of the revenue-based amount calculation, the number of assigned beneficiaries for PY 2022 would be multiplied by the estimated per capita FFS revenues determined for CY 2020 in accordance with step 2.

In step 4, we would recalculate the repayment mechanism amount by multiplying the amount determined in step 3 by the applicable percentage. Currently, that is 1 percent under the expenditure-based amount calculation, and 2 percent under the revenue-based amount calculation. Under the proposals described in section III.J.3.b.(1) of this proposed rule, the applicable percentages would be one-half percent under the expenditure-based amount calculation, and 1 percent under the revenue-based amount calculation.

We propose to modify § 425.204(f)(4)(ii) to more clearly specify the assigned population used as a multiplier in calculating the repayment mechanism amount. Under the existing regulation text at § 425.204(f)(4)(ii)(A), the potential repayment mechanism amount is a specified percentage of total per capita Medicare Parts A and B fee-for-service expenditures ''for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.'' We propose to amend paragraph (f)(4)(ii)(A) to refer to a specified percentage of total per capita Medicare Parts A and B fee-for-service expenditures ''for the ACO's assigned beneficiaries, based on expenditures *and the number of assigned beneficiaries* for the most recent calendar year for which 12 months of data are available'' (emphasis added to reflect revised text).

Under the existing regulation text at § 425.204(f)(4)(ii)(B), the potential repayment mechanism amount is a specified percentage of total Medicare Parts A and B fee-for-service revenue ''of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.'' We propose to amend paragraph (f)(4)(ii)(B) to refer to a specified percentage of total Medicare Parts A and B fee-for-service revenue ''of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, *and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available*'' (emphasis added to reflect revised text).

We also propose technical and conforming changes to the introductory text of § 425.204(f)(4)(iii). We propose to remove as unnecessary and irrelevant the text specifying that the provision applies for agreement periods beginning on or after July 1, 2019. We propose to revise the introductory text for clarity to specify that CMS would recalculate the ACO's repayment mechanism amount ''for'' the second and each subsequent performance year in the agreement period, rather than ''before'' the second and each subsequent performance year in the agreement period. We propose to make a conforming change to the introductory text of § 425.204(f)(4)(iii) to specify that CMS' recalculation of the ACO's repayment mechanism amount would be in accordance with § 425.204(f)(4)(ii) based on the certified ACO participant list for the relevant performance year, ''except that the number of assigned beneficiaries used in the calculations would be the number of beneficiaries assigned to the ACO at the beginning of the relevant performance year under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3)(i) (for ACOs under prospective assignment).''

We propose that these modifications would be effective and applicable on January 1, 2022. If finalized as proposed, these policies would be used in determining required repayment mechanism amounts for ACOs establishing a repayment mechanism arrangement to support their participation in a two-sided model beginning with performance year 2022, and in subsequent performance years, and in determining recalculated repayment mechanism amounts for performance year 2022 and subsequent performance years, as well as the determination that an eligible ACO has a one-time opportunity to decrease the amount of its repayment mechanism amount as described in section III.J.3.b.(3) of this proposed rule.

(3) Optional One-Time Repayment Mechanism Decrease for Eligible ACOs

In connection with the proposal for lowering the repayment mechanism amounts, described in section III.J.3.b.(1) of this proposed rule, we are proposing to allow certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. The purpose of this proposal is to let any ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to decrease its repayment mechanism amount before it seeks to renew its agreement under the new proposed policy, which if finalized, would otherwise be the first opportunity for the ACO to reduce its repayment mechanism amount. Along these lines, the one-time decrease would also avoid unnecessary burden that could result if ACOs seek to terminate their participation agreements early and apply to re-enter the program in order to reduce their required repayment mechanism amounts.

As discussed in section III.J.3.b.(1) of this proposed rule, if the proposed modifications to the repayment mechanism amount calculation methodology are finalized, and effective and applicable on January 1, 2022, we would ensure that the revised methodology would be used in determining repayment mechanism amounts for ACOs establishing a repayment mechanism to support their participation in a two-sided model beginning with performance 2022. Therefore, ACOs entering a two-sided model for an agreement period beginning on January 1, 2022, and ACOs with an earlier start date participating in the BASIC track's glide path and entering a two-sided model starting on January 1, 2022, would have established repayment mechanism amounts determined according to the proposed amount calculation methodology, if finalized. Therefore, we would not consider such ACOs eligible for the proposed one-time opportunity to decrease the amount of their repayment mechanism.

Under this proposal, an eligible ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, may elect to decrease the amount

of its repayment mechanism if the recalculated repayment mechanism amount for performance year 2022 is less than the existing repayment mechanism amount. To determine if an ACO is eligible to lower its repayment mechanism amount, we propose to compare the ACO's existing repayment mechanism amount with the recalculated amount of the ACO's repayment mechanism based on its certified ACO participant list for performance year 2022, calculated in accordance with § 425.204(f)(4)(iii) (including any modifications finalized to the recalculation methodology which would be effective and applicable January 1, 2022, as discussed in this proposed rule). If the recalculated repayment mechanism amount for performance year 2022 is less than the existing repayment mechanism amount, the ACO would be eligible to decrease the amount of its repayment mechanism to the recalculated amount. Under this approach, we would permit a one-time decrease in the repayment mechanism amount even for relatively small differences in dollar amounts.

We propose that CMS would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanism. If this proposal is finalized, we anticipate that we would notify an ACO of its opportunity to reduce its repayment mechanism amount after the start of performance year 2022. We also propose that an ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. We expect that the deadline for submitting the election and revised repayment documentation would be 30 days from the date of the written notice from CMS, although we recognize that there may be circumstances that necessitate a longer timeframe. CMS would review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

We propose to amend § 425.204 to add paragraph (f)(4)(v) to establish the policy and relevant procedure that would allow eligible ACOs that established a repayment mechanism to support their participation in a two-sided model beginning on July 1, 2019, January 1, 2020, or January 1, 2021, to elect to lower the amount of their repayment mechanism arrangements.

(4) Threshold for Increasing Repayment Mechanism Amounts

In accordance with § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its repayment mechanism has been increased to the amount specified by CMS.

In establishing the annual repayment mechanism amount recalculation policy in earlier rulemaking (83 FR 67930), we explained the purpose of this approach was to address changes in the ACO's composition of ACO participant TINs and the individuals who bill through the participant TINs over the course of an agreement period and to ensure the adequacy of an ACO's repayment mechanism. In establishing the annual recalculation policy (83 FR 67932), we explained that a threshold of 50 percent or $1,000,000 would likely require an increased repayment mechanism amount only for ACOs that had the largest changes in their estimated repayment mechanism value (the top 5 to 10 percent of ACOs). We believed this approach would minimize an ACO's administrative burden and financial institution fees while adjusting for meaningful changes in repayment mechanism amounts that would help protect the Medicare Trust Funds.

We continue to believe that the annual repayment mechanism amount recalculation serves an important function in identifying the need for repayment mechanism increases when an ACO's composition changes. Such changes could result in higher expenditures for the ACO's assigned beneficiaries, higher ACO participant revenue, or a larger assigned beneficiary population. Each of these changes could increase the amount of potential shared losses for an ACO under a two-sided model.

Based on our operational experience with the recalculation policy, we have found that ACOs whose recalculated repayment mechanism amount is at least 50 percent higher than their existing amount, but less than $1,000,000 more, tend to be low revenue ACOs with relatively smaller existing repayment mechanism amounts, typically less than $300,000. Further, based on our operational experience and input from ACOs and other program stakeholders, modifications to repayment mechanism arrangements to revise the amount are burdensome for ACOs. These modifications are time consuming to arrange, and can result in additional fees charged by financial institutions for ACOs to modify their arrangements, in addition to requiring ACOs to set aside additional funds (such as with escrow accounts). We believe the burden for these ACOs to increase their repayment mechanism amounts is disproportional to the benefit to CMS in the availability of additional repayment mechanism arrangement funds to support repayment of losses.

Further, we believe it is timely to revisit the amount increase thresholds under the repayment mechanism amount recalculation policy in light of our proposal described in section III.J.3.b.(1) of this proposed rule to reduce the amounts required for repayment mechanism arrangements. If we finalize our proposal to reduce by one-half the repayment mechanism amounts, the 50 percent threshold of the amount recalculation provision would be proportionally lower, and the burden for these ACOs to increase their repayment mechanism amounts would be even more disproportional to the benefit to CMS.

We believe that requiring an increase in the repayment mechanism amount if the recalculated amount for the performance year is at least $1,000,000 greater than the existing amount balances our interest in ensuring the repayment mechanism amount accounts for significant changes in an ACO's composition during its agreement period, while avoiding burdensome repayment mechanism modifications for relatively small dollar amounts. Therefore, we propose to amend the regulations at § 425.204(f)(4)(iii)(A) to remove the 50 percent threshold from the annual repayment mechanism increase threshold, such that if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, CMS would notify the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount. We anticipate this approach would reduce the number of ACOs required to annually increase their repayment mechanism amounts and would further simplify the repayment mechanism amount calculations.

We propose that this modification would be effective and applicable on January 1, 2022. If finalized as proposed, the revised threshold would be used in determining required repayment mechanism increases for performance year 2022, and subsequent performance years.

4. Reducing Shared Savings Program Application Burden

a. Background

In order to participate in the Shared Savings Program, a prospective ACO must submit an application and certify that it satisfies the eligibility and other requirements of the Shared Savings Program, including regulatory requirements to disclose prior participation. Under § 425.204(b), an ACO must disclose in its Shared Savings Program application whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Shared Savings Program under the same or a different name or is related to or affiliated with another Shared Savings Program ACO. The ACO must also disclose in the application whether the related participation agreement was terminated (voluntarily or involuntarily), the cause for prior termination, and what safeguards are in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the participation agreement. We refer to both of these disclosure requirements as the ''prior participation disclosure requirement.''

Our application evaluation criteria for renewing ACOs and re-entering ACOs are designed to prevent ACOs with a history of poor performance or a history of noncompliance with the Shared Savings Program regulations from participating in the program. Under § 425.224(b), we determine whether to approve an application based on an evaluation of several criteria, including the following: (1) Whether the ACO has a history of noncompliance with the program's requirements, including a failure to meet the quality performance standard; (2) the ACO's history of financial performance; (3) whether an ACO under a two-sided model failed to repay shared losses owed to the program; and (4) whether the ACO has demonstrated in its application that it has corrected the deficiencies that caused it to perform poorly or to be terminated.

Additionally, under § 425.204(c)(6), all applicants, including initial, renewing, and re-entering applicants, must submit as part of the application process and upon request by CMS, documents demonstrating that their ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. Such documents must include sample or form agreements and the first and signature pages of each executed ACO participant agreement. We may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO is also required to certify that each of its ACO participant agreements meet all Shared Savings Program requirements in 42 CFR part 425.

Under § 425.116(c), we also require an ACO to submit an executed ACO participant agreement for each participant at the time of its initial application, participation agreement renewal process, and when making additions to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner specified under § 425.204(c)(6) or as otherwise specified by CMS.

b. Proposed Revisions

In conducting Shared Savings Program application reviews, we have found that the document submission requirements in §§ 425.204(b) and (c)(6), and 425.116(c) substantially increase applicant burden without lending significant value to our review of an organization's application to confirm that the ACO meets the eligibility requirements for participation. We therefore propose to revise §§ 425.204(b) and (c)(6), and § 425.116(c) to reduce applicant burden.

First, we propose to modify § 425.204(b) so that the prior participation disclosure requirement is prescribed only at the request of CMS during the application process—rather than as a mandatory submission with the ACO's initial or renewal application. Under this proposal, we would continue review of an ACO's history of compliance with the Shared Savings Program regulations and the ACO's quality and financial performance results in accordance with § 425.224(b), at CMS' request.

Second, we propose to modify § 425.204(c)(6) to remove provisions requiring an ACO to submit sample ACO participant agreements during the application process. Under this proposal, sample ACO participant agreements and the first and signature pages of each executed ACO participant agreement would need to be submitted during the application process only if requested by CMS, rather than as a mandatory submission with the ACO's initial or renewal application. The ACO must still certify that the all of its ACO participant agreements comply with the regulatory requirements of the Shared Savings Program. CMS would retain the discretion to request ACO participant agreement documentation at any time during an agreement period.

Third, we propose to modify § 425.116(c) to remove provisions requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application or participation agreement renewal process. We would retain the requirement that an ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants. We believe these three proposals will collectively reduce the administrative and programmatic burden for ACOs significantly without sacrificing program integrity and reinforce that ACOs are responsible for ensuring their ACO participant agreements meet Shared Savings Program requirements.

(1) Prior Participation Requirement (§ 425.204(b))

We propose to modify § 425.204(b) so that the prior participation disclosure requirement is prescribed only at the request of CMS—rather than as a mandatory submission with the ACO's initial or renewal application. During the application cycle and for the purposes of evaluating program eligibility, CMS already determines prior participation for initial and re-entering ACO applicants by reviewing ACO- and ACO participant-level information. We screen all ACO applicants, initial ACOs and re-entering ACOs, to determine if they have participated in the Shared Savings Program, including if their prior participation agreement was terminated early (voluntarily or involuntarily). We also identify initial ACOs as re-entering ACOs if greater than 50 percent of their ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date (§ 425.20), in order to hold these ACOs accountable for their ACO participants' experience with the program.

Additionally, all ACO participants and ACO providers/suppliers undergo a rigorous screening process during the application cycle (and throughout the agreement period, if approved to participate in the program) to ensure

they meet certain program requirements. CMS' screening processes are protective of the program and provide CMS with eligibility information about individual ACO participants including: Medicare-enrollment status (§ 425.20); program integrity history (§ 425.305(a)); any participation in other Medicare shared savings initiatives (§ 425.114); and participation in other Shared Savings Program ACOs, including whether the ACO participant submitted claims used in beneficiary assignment (§ 425.306). These robust application screening processes for ACO participants and ACO providers/suppliers provides necessary information about ACOs and individual ACO participants.

We propose to revise § 425.204(b) to provide that, upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b). Under this proposal, and to ensure future compliance, we may request additional information from an ACO concerning its prior participation or the prior participation of their ACO participants or its ACO providers/suppliers. In that case, we would require the ACO to include in its response assurances describing how they will remain in compliance with program requirements—particularly as to the quality performance standard and financial performance—while completing the full term of the participation agreement. Thus, with the robust evaluation criteria of § 425.224(b) for renewing and re-entering ACOs and the application screening processes for ACO participants and ACO providers/suppliers, we believe we can effectively evaluate an ACO's prior participation and determine its suitability to participate in the program without requiring ACOs to self-identify prior participation under § 425.204(b), including the cause of termination (if any), and what safeguards have been put into place.

(2) Submission of Sample Agreements (§ 425.204(c)(6))

We propose to revise § 425.204(c)(6) to require an ACO to submit sample or form ACO participant agreement documents during the application cycle only upon request. We review sample agreements to ensure they contain the language required under § 425.116. However, it is ultimately the ACO's responsibility to ensure that all of its ACO participant agreements comply with the Shared Savings Program requirements. We have concerns that CMS review of sample participant agreements gave the incorrect impression that CMS had determined that an agreement met all regulatory requirements.

We believe that removing the requirement at § 425.204(c)(6) to submit sample agreements reduces administrative burden on both ACOs and CMS in the submission and reviewing of sample agreements. Under our proposal, we would retain the ability to request ACO sample participant agreements during the application cycle and at any point during an agreement period. Although we would not expect to routinely request during the application cycle that an ACO submit copies of ACO participant agreement documentation, it could be particularly useful in the case of ACOs that have a history of noncompliance with § 425.116 or other program requirements.

We would retain the requirement in § 425.204(c)(6) that the ACO must certify that each of its ACO participant agreements comply with the requirements of the Shared Savings Program. We believe this modification to § 425.204(c)(6) more clearly prescribes that the ACO is ultimately responsible for compliance with all program requirements.

(3) Submission of Executed Participant Agreements (§ 425.116(c))

Lastly, we propose to modify § 425.116(c) to remove language requiring an ACO to submit an executed ACO participant agreement for each ACO participant at the time of its initial application and during the participation agreement renewal process. The submission of agreements at the time of initial application will be governed by § 425.204(c)(6) and does not need to be addressed in § 425.116(c). Moreover, unless there have been amendments to an ACO participant agreement, we would not need to collect for a second time executed ACO participant agreements with ACO participants who are actively participating in an ACO at the time it is applying to renew its participation agreement with the program. In our experience, neither ACOs nor their ACO participants have frequently raised concerns about continuing participation with an ACO into a new agreement period, nor notified CMS of changes to ACO participant agreements. An ACO must notify CMS within 30 days after the termination of an ACO participant agreement in accordance with § 425.118(b)(2).

We would retain the remainder of § 425.116(c), which requires ACOs to submit ACO participant agreements when requesting additions to their ACO participant lists in accordance with § 425.118 and specifies that the agreements may be submitted in the form and manner specified under § 425.204(c)(6). We note that although ACOs may request additions to an ACO participant list at specified times during a performance year, all approved ACO participant list additions become effective on January 1 of the following performance year (§ 425.118(b)(1)(ii)).We continue to find value in reviewing executed ACO participant agreements in these circumstances. ACO participant additions may take the form of an initial applicant or renewing ACO submitting proposed ACO participants (that may or may not have participated with another ACO), or a currently participating ACO adding proposed participants (that may or may not be participating with another ACO) to their ACO participant list. Collecting executed agreements (which may include collecting only the first and signature page(s) under § 425.204(c)(6)) for additions to an ACO's participant list provides CMS with evidence that the ACO and the participant are each aware of the agreement and are participating together in the Shared Savings Program. Should CMS need to review executed participant agreements other than when ACOs are adding to their list of ACO participants, CMS can request them at that time under proposed § 425.206(c)(6) or under its audit authority in accordance with § 425.314.

5. Beneficiary Information Notices for ACOs With Prospective Assignment

a. Background

To ensure full transparency between Shared Savings Program ACOs and the beneficiaries they serve, § 425.312(a)(1) provides that an ACO must ensure that Medicare FFS beneficiaries are notified about all of the following: (1) That its ACO providers/suppliers are participating in the Shared Savings Program; (2) the beneficiary's opportunity to decline claims data sharing; and (3) the beneficiary's ability to, and the process by which, he or she may identify or change identification of the individual he or she designated as their primary clinician for purposes of voluntary alignment. Under § 425.312(a)(2)(i), we require this information to be furnished by an ACO participant posting signs in its facilities

and, in settings in which beneficiaries receive primary care services, making standardized written notices available upon request.

In the December 2018 final rule, we specified at § 425.312(a)(2)(ii) that, during the performance year beginning on July 1, 2019 and each subsequent performance year, the information must also be furnished by an ACO or ACO participant providing each beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS. While we continued to encourage ACO participants to distribute the notice to beneficiaries at the point of care to address any beneficiary questions or concerns, the flexibility was granted so that an ACO or its ACO participants could distribute beneficiary notifications through electronic transmission (such as email) or mail. We note that, regardless of the method of notification used, CMS may review evidence related to the dissemination of the beneficiary information notice at any time under its audit authority in accordance with § 425.314.

In the December 2018 final rule, we finalized requirements to further strengthen the beneficiary notification requirements. Specifically, we made changes to permit an ACO (not just its ACO participants) to disseminate the beneficiary information notice to beneficiaries, to require the notice to be provided prior to or at the first primary care visit of each performance year, and to permit the distribution of the notice through electronic transmission (such as email) or mail. We believe the modifications made to the beneficiary notification requirements in the December 2018 final rule help empower beneficiary choice, support beneficiary engagement, improve transparency, and ensure that beneficiaries are informed about the program and how it may affect their care and the use of their data. In making the decision to provide a CMS-approved template, we aimed to make the notification a comprehensive resource that compiled information about the program and what participation in the program means for beneficiary care. In addition, we believed that the availability of CMS-approved beneficiary notification templates would mitigate the potential for administrative and operational burden on providers.

b. Proposed Revisions

In considering the several different iterations of the beneficiary notice requirement over the history of the program,[102] we have concluded that the current requirement to provide beneficiary notifications prior to or at the first primary care visit of the performance year is overly broad with respect to ACOs that have selected the prospective assignment methodology. Such ACOs are currently required to provide the beneficiary notice to beneficiaries who will never be assigned to the ACO for the performance year.

As noted earlier, the intention of the beneficiary notification is to empower beneficiaries, encourage beneficiary engagement, and improve transparency. For an ACO participating under the prospective assignment methodology, described in § 425.400(a)(3), all of the ACO's beneficiaries are assigned at the beginning of the performance year. Under § 425.704(d)(1)(ii), such ACOs may request beneficiary identifiable claims data only for FFS beneficiaries that appear on the ACOs' prospective assignment list at the beginning of the performance year and who have not opted out of data sharing. Beneficiaries who are not assigned to an ACO that has selected prospective assignment will never be assigned to the ACO during the relevant performance year and will not be subject to data sharing with the ACO. In short, such beneficiaries have no need to receive any information about the Shared Savings Program at the beginning of a performance year. Therefore, we believe that it would cause unnecessary confusion for beneficiaries to receive the notice if they are not prospectively assigned to an ACO because the notice describes details that will not apply to them (for example, information on data sharing and the SNF 3-day rule waiver).

In contrast, for ACOs under preliminarily prospective assignment with retrospective reconciliation, the preliminary prospective assignment list provided to the ACO at the beginning of the performance year does not include all FFS beneficiaries who may ultimately be assigned to the ACO. As such, we continue to believe all FFS beneficiaries receiving primary care services from ACO providers and/or suppliers should receive the notice. This ensures that all beneficiaries ultimately assigned to the ACO would be informed of their right to decline data sharing.

We propose to amend § 425.312(a)(2) to set forth different beneficiary notification obligations depending on the assignment methodology selected by the ACO. Specifically, we propose at § 425.312(a)(2)(ii) to provide that, in the case of an ACO that has selected preliminary prospective assignment, the ACO or ACO participant must provide the standardized written beneficiary notice to each fee-for-service beneficiary prior to or at the first primary care visit of the performance year. We propose to add at § 425.312(a)(2)(iii) that, in the case of an ACO that has selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary prior to or at the first primary care visit of the performance year.

We continue to believe that the requirement to provide the beneficiary information notice is important to empowering beneficiaries and providing important information about their care, but we also understand that the current requirement of disseminating the beneficiary information notice annually may have the potential to be overly burdensome to ACOs and/or their ACO participants. We seek comment from stakeholders on whether we should modify the frequency with which the beneficiary information notice must be furnished, for example, by reducing the frequency of the existing requirement from annually to once per agreement period. We expect that ACOs would be required to provide the notice to their FFS beneficiaries, based on assignment methodology, including any beneficiaries who seek care from ACO providers/suppliers throughout the agreement period. ACOs would also be responsible for issuing the beneficiary information notice during subsequent agreement periods, reminding assigned beneficiaries of their participation in the Shared Savings Program. Beneficiaries would continue to be able to modify their decision on whether to allow data sharing at any point. While we have received feedback from program stakeholders regarding the current annual requirement being too frequent, potentially confusing beneficiaries, and increasing burden on ACOs, reducing the frequency to once per agreement period may ultimately be too infrequent, given the many changes a beneficiary may experience with their health and life in general in that span of time. It is our goal to provide the notifications in a way that will continue to empower and inform beneficiaries without overwhelming or confusing them with

[102] We have made several revisions to the beneficiary notification provisions over time. Refer to the November 2011 final rule, 76 FR 67802, 67945 through 67946 (establishing the requirement for beneficiary notifications). Refer to the June 2015 final rule, 80 FR 32692, 32740 through 32743 (establishing requirements for ACO to use a CMS-approved template for beneficiary notifications, allowing ACOs to obtain claims data for beneficiaries, and establishing an avenue for beneficiaries to opt out of data-sharing).

information. We encourage stakeholders to provide feedback on this suggestion, as well as other suggestions they may have in the spirit of burden reduction with regard to the beneficiary notification requirement as well as transparency and beneficiary engagement.

6. Seeking Comment on Considerations Related to the Use of Regional FFS Expenditures in Establishing, Adjusting, Updating, and Resetting the ACO's Historical Benchmark

a. Background on the Shared Savings Program Benchmarking Methodology

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. This benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, as estimated by the Secretary. The benchmark shall be reset at the start of each agreement period. In addition to the statutory benchmarking methodology established in section 1899(d) of the Act, section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models, including payment models that would use alternative benchmarking methodologies, if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under the Medicare program and that the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model.

In the November 2011 final rule establishing the Shared Savings Program, we adopted policies for establishing, updating, and resetting the benchmark at § 425.602. The Shared Savings Program's regulations have since evolved to include different benchmarking methodologies, including modifications to § 425.602, and the addition of separate benchmarking policies for ACOs entering a second or subsequent agreement period at § 425.603. Benchmarking policies applicable to all ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, are specified in § 425.601. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; and December 2018 final rule, 83 FR 68005 through 68030).

For details on the benchmarking calculations, we refer readers to the regulations at 42 CFR part 425, subpart G, as well as the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #9, February 2021), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-0*.

In the following discussion, we summarize select aspects of the Shared Savings Program's benchmarking methodology and related concerns that have been expressed by ACOs and other stakeholders. We specify some considerations based on our initial analyses of these issues, and seek comment on considerations that may inform future policy developments. However, we note that we are still in the process of monitoring program calculations based on the initial performance years of experience under the new participation options and program modifications that were adopted as part of the Pathways to Success rulemaking and are applicable for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, including changes to the benchmarking methodology (finalized in the December 2018 final rule (83 FR 67816)). In addition, we are also monitoring the impact of any anomalies in Medicare FFS expenditures and healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 Public Health Emergency, which we anticipate could further inform our considerations of future modifications to Shared Savings Program benchmarking policies (see for example, discussion in the CY 2021 PFS final rule, 85 FR 84770 through 84785).

b. Request for Comment on Calculation of the Regional Adjustment and Blended National-Regional Growth Rates for Trending and Updating the Benchmark

In calculating the historical benchmark, CMS uses historical expenditures for the ACO's assigned beneficiaries, as well as factors based on regional FFS expenditures, factors based on national FFS expenditures, and factors based on a blend of national and regional FFS expenditures. As we have described in earlier rulemaking, incorporating regional expenditures into benchmark calculations makes the ACO's cost target more independent of its historical expenditures and more reflective of FFS spending in its region (see for example, 81 FR 37950, 37951 and 37955). We have also acknowledged in earlier rulemaking that the incorporation of factors based on regional FFS expenditures into ACO benchmarks will have varying effects on ACOs depending on each organization's individual circumstances (see for example, 81 FR 37950, 37954 through 37957, and 81 FR 37975 through 37977; and 83 FR 67816, 68017 and 68026).

In accordance with § 425.601(a)(8), CMS adjusts historical benchmark expenditures by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) by a percentage of the difference between the average per capita expenditure amount for the ACO's regional service area and the ACO's historical benchmark amount (referred to herein as the ''regional adjustment''). The percentage that is applied in calculating the regional adjustment is determined in accordance with § 425.601(f) and depends on whether the ACO has lower or higher spending compared to the ACO's regional service area and the agreement period for which the ACO is subject to the regional adjustment, according to the phase-in schedule of the applicable weights. CMS caps the per capita dollar amount of the regional adjustment for each Medicare enrollment type at a dollar amount equal to ±5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program in benchmark year (BY) 3 for assignable beneficiaries (as defined in § 425.20) in that Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

In accordance with § 425.601(a)(5), in establishing and resetting an ACO's benchmark, CMS trends forward expenditures for each benchmark year (BY1 and BY2) to BY3 dollars using a blend of national and regional growth rates, making separate calculations for each Medicare enrollment type. Similarly, in accordance with § 425.601(b), CMS updates the historical benchmark annually for each year of the agreement period using a blend of national and regional growth rates between BY3 and the performance year. As described in the December 2018 final rule (83 FR 68024 through 68030), we

used our statutory authority under section 1899(i)(3) of the Act to adopt this policy under which we update the historical benchmark using a blend of national and regional growth rates, rather than the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act. CMS accounts for an ACO's penetration in its region when calculating the national-regional blended growth rates, by placing a higher weight on the national component of the blend and a lower weight on the regional component as the ACO's penetration in its region increases.

In determining regional FFS expenditures, CMS uses average county FFS expenditures for assignable beneficiaries, including the ACO's assigned beneficiaries, in each county in the ACO's regional service area for the 12-month calendar year corresponding to the relevant benchmark or performance year.[103] [104] CMS weights these county-level FFS expenditure amounts by the proportion of the ACO's assigned beneficiaries residing in each county, with all calculations performed separately by Medicare enrollment type. Refer to § 425.601(c) (calculating county expenditures) and (d) (calculating regional expenditures).

ACOs and other program stakeholders have expressed concerns with the approach to determining regional FFS expenditures using a population of assignable beneficiaries that includes the ACO's assigned beneficiaries, including with respect to the impact on the calculation of the regional adjustment and the blended national-regional growth rate used to trend and update an ACO's historical benchmark, suggesting this policy results in relatively lower benchmarks for ACOs, particularly ACOs with high market penetration in their regional service area, which may tend to be ACOs located in rural areas.[105] For example, the National Association of ACOs' (NAACOS') summary ''Fixing the Rural Glitch'' explains its belief that by including the costs of all beneficiaries in the regional adjustment—both those assigned to the ACO and those who are not—CMS penalizes an ACO for reducing costs relative to its regional competitors. That is, as an ACO reduces the costs of its own assigned beneficiaries, it also reduces the average regional costs. According to NAACOS, this will ultimately reduce savings for efficient ACOs in all areas, but the effect may be most dramatic for rural ACOs because they will tend to care for a greater portion of their region's total beneficiary population than an urban ACO.[106] As another example, Aledade suggests that incorporating factors based on regional FFS expenditures into the Shared Savings Program's benchmarking methodology systemically penalizes ACOs with a large market share when they reduce costs, leading to disparate payments to ACOs with identical performance.[107] ACOs and other program stakeholders have suggested that CMS remove the effects of the ACO's own performance from factors based on regional FFS expenditures, such as by excluding an ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures.[108] Other alternatives that have been suggested to address these concerns include capping an ACO's penetration in the region at 50 percent by Medicare enrollment type, or expanding the ACO's region.[109] In recent years, legislative changes have been introduced, which if enacted would require the removal of the ACO's assigned beneficiaries from regional expenditure calculations.[110] [111] We appreciate ACOs and other program stakeholders bringing their concerns, and suggested alternatives, to our attention. We have begun to analyze these concerns about the use of factors based on regional FFS expenditures in calculating ACO benchmarks, and to consider possible modifications to the Shared Savings Program's benchmarking methodology to ensure the sustainability of the program's financial models. We note that any such modifications would need to be adopted through notice and comment rulemaking.

In this section of this proposed rule we discuss some of our considerations based on our initial analyses of stakeholders' concerns. We continue to investigate these concerns and perform additional simulations. We seek comment on these considerations and other related issues, as well as suggested approaches to modifying the program's benchmarking methodology, which could inform future rulemaking.

There may be several possible approaches that we could consider for removing an ACO's assigned beneficiaries from the assignable beneficiary population used in regional expenditure calculations, which would vary in the degree of additional program calculations and the level of complexity. We simulated the impact of removing an ACO's assigned beneficiaries from the regional expenditure calculations using an approach that would pose relatively limited operational burden and would leverage data elements already computed under the current benchmarking methodology. This approach relies on the premise that per capita risk-adjusted regional FFS expenditures for all assignable beneficiaries in an ACO's regional service area (a) can be interpreted as a weighted average of per capita risk-adjusted FFS expenditures for the

[103] Assignable beneficiary, as defined in § 425.20, means a Medicare fee-for-service beneficiary who receives at least one primary care service with a date of service during a specified 12-month assignment window from a Medicare-enrolled physician who is a primary care physician or who has one of the specialty designations included in § 425.402(c).

[104] The ACO's regional service area, as defined in § 425.20, means all counties where one or more beneficiaries assigned to the ACO reside.

[105] See for example the CY 2021 PFS final rule, summarizing commenters' concerns about the program's benchmarking methodology, received in response to modifications to Shared Savings Program policies that were adopted in the May 8, 2020 COVID–19 IFC to address the impact of the COVID–19 PHE, although we noted these comments went beyond the modifications to the program's established in that IFC (85 FR 84783 through 84785).

[106] See NAACOS, Fixing the Rural Glitch, available at *https://www.naacos.com/assets/docs/pdf/2021/RuralGlitchExplainer.pdf.*

[107] Aledade, ''Opportunities for 2022 Improvements to MSSP ACOs in the Physician Fee Schedule'' (June 2021), provided as a document during E.O. 12866 Meeting (CMS–1751), available at *https://mobile.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0938-AU42&meetingId=49323&acronym=0938-HHS/CMS.*

[108] See for example, 85 FR 84784; see also, NAACOS, Fixing the Rural Glitch, available at *https://www.naacos.com/assets/docs/pdf/2021/RuralGlitchExplainer.pdf.*

[109] See for example, Aledade, ''Opportunities for 2022 Improvements to MSSP ACOs in the Physician Fee Schedule'' (June 2021), provided as a document during E.O. 12866 Meeting (CMS–1751), available at *https://mobile.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0938-AU42&meetingId=49323&acronym=0938-HHS/CMS.*

[110] See S.2648—Rural ACO Improvement Act, 116th Congress (2019–2020), available at *https://www.congress.gov/bill/116th-congress/senate-bill/2648/text* (including a provision on Exclusion Of Assigned Beneficiaries In Certain Circumstances Including Determination Of Regional Adjustments), and H.R. 5212—Accountable Care in Rural America Act, 116th Congress (2019–2020), available at *https://www.congress.gov/bill/116th-congress/house-bill/5212/text.*

[111] See also, Letter from NAACOS et al., to Representatives Arrington, DelBene, Kelly, Bera, O'Halleran, Sewell, Dunn and Gooden (June 15, 2021), describing the introduction of H.R. 3746, the Accountable Care in Rural America Act. Available at *https://www.naacos.com/naacos-and-12-others-write-congress-in-support-of-the-accountable-care-in-rural-america-act-h-r-3746-.* H.R. 3746—117th Congress (2021–2022), available at *https://www.congress.gov/bill/117th-congress/house-bill/3746/text?r=58&s=1* (text had not been received as of 07/05/21).

ACO's assigned beneficiaries (b) and per capita risk-adjusted FFS expenditures for assignable beneficiaries in the region who are not assigned to the ACO (c), where the weight on (b) is the ACO's regional market share [112] and the weight on (c) is one minus the ACO's regional market share. Shown as an equation this is:

(a) = [(b) × (ACO's regional market share)] + [(c) × (1 − ACO's regional market share)].

Thus, to remove the ACO's assigned beneficiaries from the regional expenditure calculation, we would insert the applicable values into the above equation and solve for (c) by rearranging the equation as follows:

(c) = {(a) − [(b) × (ACO's regional market share)]}/(1 − ACO's regional market share).

By using such ACO- and regional-level values, this approach, performed separately by Medicare enrollment type, would avoid the need to calculate individualized ACO county-level risk-adjusted expenditures. We seek comment on the approach we have outlined, or alternative approaches to calculating regional FFS expenditures without an ACO's assigned beneficiaries. In particular, we seek comment on specific approaches that would strike the balance of achieving the desired outcome of removing the ACO's assigned beneficiaries from program calculations without introducing an inordinate amount of operational and administrative complexity such that the steps and data included in the calculations can be understood by ACOs and other program stakeholders, and the potential for calculation errors is minimized.

We performed initial simulations, for a subset of Shared Savings Program ACOs, using data for the 6-month performance year starting on July 1, 2019 (sometimes referred to as PY 2019A), for which expenditures were determined based on expenditures for CY 2019, to observe the effects of potential modifications to the benchmarking methodology. In performing these simulations, we used the aforementioned approach for removing expenditures for the ACO's assigned beneficiaries from the calculation of regional FFS expenditures, by removing the impact of an ACO's assigned beneficiaries from the assignable population as weighted by the ACO's regional market share. Specifically, we simulated the effects on the per capita updated benchmark of several alternate policies that would remove an ACO's assigned beneficiaries from regional expenditures used to trend and update the benchmark (either alone or as part of a national-regional blend) or from regional expenditures used to calculate the regional adjustment, or from both. When looking at average impacts by quintile of the ACO's penetration in its regional service area (that is, market share) and rural or non-rural status, the various alternatives resulted in estimated increases in the updated benchmark by amounts ranging from 0.1 percent to 1.4 percent, with ACOs with higher market shares tending to see slightly higher average increases than ACOs with lower market shares and rural ACOs seeing slightly higher average increases than non-rural ACOs. We also observed that some ACOs experienced decreases in their benchmark amounts, ranging from −0.02 percent to −1.5 percent under these simulations of alternate benchmarking policies. We note that additional analysis would be needed to consider the impact of such policies on a broader set of ACOs participating in the Shared Savings Program, to include ACOs that did not participate in a 6-month performance year from July 1, 2019, through December 31, 2019. We seek comment on this estimated range of impacts on ACO benchmark values, and on the potential mixed effects on ACOs that could result from modifications to the benchmarking methodology.

In considering alternative benchmarking methodologies to address ACOs' penetration in their regional service areas, we believe it is important to consider what would constitute heavy penetration by an ACO in its regional service area, and the extent to which market penetration should be considered in benchmark calculations. Based on preliminary analysis of data for CY 2019 using PY 2021 ACO Participant Lists for all ACOs participating in the program as of January 1, 2021, the median ACO regional market share was approximately 16.2 percent, with a minimum of 0.9 percent and a maximum of 59.2 percent. Further, 90 percent of ACOs had a regional market share of less than 37.8 percent, and 80 percent of ACOs had a regional market share of less than 29.3 percent. Accordingly, we seek comment on what would constitute heavy penetration in the ACO's regional service area and how removing the ACO's assigned beneficiaries from regional calculations, dependent on the level of penetration, could either increase or decrease the ACO's benchmark. We also seek comment on approaches that could strike a balance between adjusting program policies to address impacts on potentially few ACOs that are heavily penetrated in their regional service area while maintaining stability for most ACOs that have relatively low penetration in their regional service area.

We seek comment on the following considerations, and other possible unintended consequences that could result from removing an individual ACO's assigned beneficiaries from regional calculations.

- Would this approach create incentives for ACOs to have assigned beneficiaries who are healthier than the remaining comparison population that is the basis for benchmark factors based on regional FFS expenditures (so as to yield a higher benchmark), which could lead ACOs to seek out healthier beneficiaries and avoid at-risk or higher-cost beneficiaries?

++ Would this approach incent the formation of large ACOs within a particular market to obtain the most competitive benchmarks resulting in market consolidation, and discourage participation by relatively smaller ACOs, thus increasing costs for the Medicare Trust Funds if CMS pays larger amounts of shared savings to ACOs that have consolidated to take advantage of the ability to attract more low-cost beneficiaries in their region?

++ Would a change in the regional benchmarking methodology encourage ACOs to avoid at-risk or higher-cost beneficiaries and potentially exacerbate inequities in access to health care?

- We seek comment on the potential for negative impacts on ACOs that serve larger proportions of medically complex beneficiaries such as ACOs whose assigned beneficiary populations include larger proportions of beneficiaries who are medically complex and cared for in ambulatory or home-based settings or who reside in long term care facilities resulting from an approach that removes the ACO's assigned beneficiaries from the assignable beneficiary population used to determine regional FFS expenditures. Would such an approach yield a benchmark so low that such ACOs have little incentive to participate in the Shared Savings Program?

- Would removing an individual ACO's assigned beneficiaries result in regional FFS expenditures based on very small populations, thus introducing significant variability into

[112] What is referred to here as the ''ACO's regional market share'' is the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO, which is the weight that it is applied to the national component of the national-regional blend under § 425.601(a)(5)(iv) and (v).

regional FFS expenditure trends used in benchmark calculations?

Additionally, we seek comment on whether removal of an ACO's assigned beneficiaries from regional FFS expenditure calculations would bring about a need to remove ACO assigned beneficiaries from other Shared Savings Program financial calculations based on a broader Medicare population, including factors based on national FFS expenditures, which are used in calculating blended national and regional expenditure trend and update factors, truncation points used in calculating benchmark and performance year expenditures, and the 5 percent cap on the regional adjustment.

We also seek comment on using other approaches to calculating benchmarks under the Shared Savings Program. In particular, we seek comment on alternatives to determining regional FFS expenditures that would reduce the influence of an ACO's assigned beneficiaries on regional expenditure calculations, such as basing these expenditures on a larger geographic area, including using state-level data, Core-Based Statistical Area (CBSA)-level data, or a combination of data for these larger geographic areas and county-level data (such as blended county/state regional expenditures). We also seek comment on alternative benchmarking methodologies that may incorporate data sources other than Medicare FFS expenditure trends, such as by incorporating factors based on Medicare Advantage rates, or other published trends.

We seek comment on considerations related to the potential use of our authority under section 1899(i)(3) of the Act to implement suggested modifications to the benchmarking methodology, in particular alternative approaches to updating the historical benchmark or other alternative benchmarking methodologies that diverge from the requirements of section 1899(d)(1)(B)(ii) of the Act, since to do so we must determine that the alternative payment methodology will improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures.

We also note that for each calendar year, CMS releases two public use files (PUFs): (1) County-level Aggregate Expenditure and Risk Score Data on Assignable Beneficiaries PUF, and (2) Number of ACO Assigned Beneficiaries by County PUF. These files are available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/SSPACO/SSP_Benchmark*. Stakeholders may find this data helpful to inform their consideration of these issues.

c. Request for Comment on the Shared Savings Program's Risk Adjustment Methodology

CMS takes into account changes in severity and case mix of the ACO's assigned beneficiary population when establishing the benchmark and also in adjusting the benchmark each performance year. In accordance with § 425.601(a)(3), in establishing the benchmark, CMS adjusts expenditures for changes in severity and case mix using prospective HCC risk scores. Pursuant to § 425.601(a)(10), CMS further adjusts the ACO's historical benchmark at the time of reconciliation for a performance year to account for changes in severity and case mix for the ACO's assigned beneficiary population between BY3 and the performance year (refer to § 425.601(a)(10); § 425.605(a)(1), (a)(2); § 425.610(a)(2), (a)(3)). In making this risk adjustment, CMS makes separate adjustments for the population of assigned beneficiaries in each Medicare enrollment type used in the Shared Savings Program (ESRD, disabled, aged/dual eligible, aged/non-dual eligible). CMS uses CMS–HCC prospective risk scores to adjust the historical benchmark for changes in severity and case mix for all assigned beneficiaries, subject to a cap of positive 3 percent for the agreement period. This cap is the maximum increase in risk scores allowed for each agreement period, such that any positive adjustments between BY3 and any performance year in the agreement period cannot be larger than 3 percent. That is, the risk ratios (ratio of performance year risk score to the BY3 risk score) applied to historical benchmark expenditures to capture changes in health status between BY3 and the performance year will never be higher than 1.030 for any performance year over the course of the agreement period. This cap is applied separately for the population of beneficiaries in each Medicare enrollment type.[113]

ACOs and other stakeholders have expressed concerns that the program's methodology for capping any increase in the risk adjustment to the historical benchmark, such that any positive adjustment between benchmark year 3 and any performance year in the agreement period cannot be larger than 3 percent, does not account for risk score growth in the ACO's regional service area, and thereby penalizes ACOs.[114] [115] In earlier rulemaking, commenters expressed that the 3 percent cap on risk score increases was especially problematic for ACOs whose regional service area includes a population of beneficiaries whose risk scores rise more than the cap. One commenter encouraged CMS to adopt a policy of applying a cap on risk score growth after accounting for regional increase in risk scores (85 FR 84784).

We seek comment on—

- Approaches, generally, to improving the risk adjustment methodology for the Shared Savings Program, and specifically for ACOs with medically-complex, high-cost beneficiaries.
- Approaches to risk adjustment that would balance the need for accurate and complete coding, while protecting against incentivizing coding intensity initiatives by ACO participants and ACO providers/suppliers (which may be even more problematic for ACOs with high penetration in their region) that increase risk score growth above the existing 3 percent cap.
- Alternate approaches that would increase the cap on an ACO's risk score growth in relation to risk score growth in the ACO's regional service area, such as:

++ Allowing the ACO risk score growth cap to increase by a percentage of the difference between the current 3 percent cap and risk score growth in the ACO's regional service area. In this alternate approach, the percentage applied would be equal to 1 minus the ACO's regional market share. This approach would raise the existing cap while limiting the ability for ACOs with high penetration in their region to increase their cap by engaging in coding intensity initiatives that raises the regional risk score.

++ Setting the ACO risk score growth cap at some level between the existing 3 percent risk score cap and the regional risk score growth, which would account for a portion of the regional risk score growth that exceeds the current cap.

- The potential interactions between policies to remove assigned

[113] Refer to the December 2018 final rule (83 FR 68007 through 68013), section on ''Risk Adjustment Methodology for Adjusting Historical Benchmark Each Performance Year''. See also, the Medicare Shared Savings Program, Shared Savings and Losses and Assignment Methodology Specifications (version #9, February 2021), section 3.6, available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-0*.

[114] 85 FR 84783 through 84785.

[115] Aledade, ''Opportunities for 2022 Improvements to MSSP ACOs in the Physician Fee Schedule'' (June 2021), provided as a document during E.O. 12866 Meeting (CMS–1751), available at *https://mobile.reginfo.gov/public/do/viewEO12866Meeting?viewRule=false&rin=0938-AU42&meetingId=49323&acronym=0938-HHS/CMS*.

beneficiaries from the assignable beneficiary population used to calculate regional FFS expenditures and growth rates (described elsewhere in this section of this proposed rule), and policies addressing regional risk score growth.

K. Medicare Ground Ambulance Data Collection System

1. Background on Ambulance Services

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established under section 1834(l) of the Act. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610 of the regulations. In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. The AFS also incorporates two permanent add-on payments and three temporary add-on payments to the base rate and/or mileage rate. The two permanent add-on payments at § 414.610(c)(5)(i) are: (1) A 50 percent increase in the standard mileage rate for ground ambulance transports that originate in rural areas where the travel distance is between 1 and 17 miles; and (2) a 50 percent increase to both the base and mileage rate for rural air ambulance transports. The three temporary add-on payments at sections 1834(l)(12)(A) and (13)(A) of the Act and § 414.610 are: (1) A 3 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in ''super rural'' areas. Section 50203(a)(1) and (2) of the Bipartisan Budget Act (BBA) of 2018 (Pub. L. 115–123, February 9, 2018) includes an extension of the temporary add-on payments through December 31, 2022.

Our regulations relating to coverage of and payment for ambulance services are set forth at 42 CFR part 410, subpart B, and 42 CFR part 414, subpart H.

2. Statutory Requirements for the Ground Ambulance Providers and Suppliers To Submit Cost and Other Information

Section 50203(b) of the BBA of 2018 added paragraph (17) to section 1834(l) of the Act, which requires ground ambulance providers of services and suppliers to submit cost and other information. Specifically, section 1834(l)(17)(A) of the Act requires the Secretary to develop a data collection system (which may include use of a cost survey) to collect cost, revenue, utilization, and other information determined appropriate by the Secretary for providers and suppliers of ground ambulance services. Section 1834(l)(17)(B)(i) of the Act requires the Secretary to specify the data collection system by December 31, 2019, and to identify the ground ambulance providers and suppliers that would be required to submit information under the data collection system. Section 1834(l)(17)(D) of the Act requires that beginning January 1, 2022, the Secretary apply a 10 percent payment reduction to payments made under section 1834(l) of the Act for the applicable period to a ground ambulance provider or supplier that is required to submit information under the data collection system and does not sufficiently submit such information. The term ''applicable period'' is defined under section 1834(l)(17)(D)(ii) of the Act to mean, for a ground ambulance provider or supplier, a year specified by the Secretary not more than 2 years after the end of the period for which the Secretary has made a determination that the ground ambulance provider or supplier has failed to sufficiently submit information under the data collection system. Section 1834(l)(17)(F) of the Act requires that no later than March 15, 2023 and as determined necessary by MedPAC, MedPAC must submit a report to Congress on the information submitted by the ground ambulance providers and suppliers through the data collection system on the adequacy of payments for ground ambulance services and geographic variations in the cost of furnishing such services.

In the CY 2020 PFS final rule (84 FR 62864 through 62897), we implemented section 1834(l)(17) of the Act and codified regulations governing data reporting by ground ambulance providers and suppliers (referred collectively as ''ground ambulance organizations'') at §§ 414.601, 414.605, 414.610(c)(9), and 414.626. In the CY 2020 PFS final rule (84 FR 62863 through 629897), we finalized a data collection system that collects detailed information on ground ambulance provider and supplier characteristics including service areas, service volume, costs, and revenue through a data collection instrument, commonly referred to as the Medicare Ground Ambulance Data Collection Instrument, via a web-based system. This instrument includes the specific questions that will be asked of ground ambulance organizations about the total service volume, costs, and revenue associated with a provider or supplier's entire ground ambulance organization in such a way that MedPAC could use to calculate an average cost per ground ambulance transport. We refer the reader to our CY 2020 PFS final rule (84 FR 62863 through 62897) for more specifics on the establishment of the Medicare Ground Ambulance Data Collection System.

3. Proposed Revisions to the Medicare Ground Ambulance Data Collection Instrument

As described in the CY 2020 PFS final rule (84 FR 62867), the Medicare Ground Ambulance Data Collection Instrument uses screening questions and skip patterns so that it is applicable to all ground ambulance organizations regardless of their size, scope of operations and services offered, and structure. We stated that we believe this approach is easier to navigate and less time consuming to complete than a cost report template or instrument and that it minimizes respondent burden by directing ground ambulance organizations to only view and respond to questions that apply to their specific type of organization, all while still collecting the information required in sections 1834(l)(17)(A) of the Act.

The CY 2020 PFS final rule provided a detailed overview of the elements of the data collection instrument, including questions to collect information on costs, revenues, utilization (which CMS defines for the purposes of the data collection instrument as service volume and service mix), as well as the characteristics of ground ambulance organizations. Table 27 includes a high-level summary of the 13 sections of the Medicare Ground Ambulance Data Collection Instrument.

TABLE 27: Components for the Data Collection Instrument

Component (Data Collection Instrument Section)	Broad Description
General survey instructions (1)	Information on background and motivation for data collection, instructions for navigating the instrument, and links for questions and other resources.
Ground ambulance organization characteristics (2-4)	Information regarding the identity of the organization and respondent(s), service area, ownership, response time, and other characteristics; broad questions about offered services to serve as screening questions.
Utilization: Ground ambulance service volume and service mix (5 and 6)	Number of responses and transports, level of services reported by HCPCS code.
Costs (7-12)	Information on all costs partially or entirely related to ground ambulance services.
• Staffing and Labor Costs (7)	Hours and costs associated with EMTs, administrative staff, and facilities staff; separate reporting of volunteer staff and associated costs.
• Facilities Costs (8)	Number of facilities; annual cost of ownership, insurance, maintenance, and utilities.
• Vehicle Costs (9)	Number of ground ambulances; number of other vehicles used in ground ambulance responses; annual cost of ownership; total fuel, maintenance, and insurance costs.
• Equipment & Supply Costs (10)	Capital medical and non-medical equipment; medical and non-medical supplies and other equipment.
• Other Costs (11)	All other costs not reported elsewhere.
• Total Cost (12)	Total costs for the ground ambulance organization included as a way to cross-check costs reported in the data collection instrument.
Revenue (13)	Revenue from health insurers (including Medicare); revenue from all other sources including communities served.

We continue to receive ad hoc questions and feedback related to the Medicare Ground Ambulance Data Collection System and the Medicare Ground Ambulance Data Collection Instrument via three primary channels. First, we receive email and other communication from ground ambulance organizations via the CMS Ambulance Data Collection email inbox (*AmbulanceDataCollection@cms.hhs.gov*) and through other channels (for example, inquiries sent by organizations to Medicare Administrative Contractors (MACs) and then forwarded to CMS). These emails and other communications often include questions seeking clarification of instrument questions and their applicability to specific ground ambulance organization scenarios and context. We continue to update a Medicare Ground Ambulance Data Collection System Frequently Asked Questions (FAQ) document with answers to commonly asked questions. This document is available on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*. Through review of questions and feedback, we have identified some instances where a clarification to the instrument language itself will likely be more useful and less burdensome to respondents than having to respond with reference to the FAQ document. Second, our contractor also asked a small number of ground ambulance organizations to complete and provide feedback on a paper version of the Medicare Ground Ambulance Data Collection Instrument. This feedback was helpful to identify some additional opportunities for clarification. Third, we continue to identify opportunities to clarify instructions and correct a small number of typos as we work to develop the web-based, programmed version of the Medicare Ground Ambulance Data Collection Instrument.

Based on information that we received via the three sources described above, we are proposing the following changes and clarifications to the Medicare Ground Ambulance Data Collection Instrument. The proposed changes and clarifications aim to reduce burden on respondents, improve data quality, or both.

a. Proposed Change to the Shared Services Questions in Section 2 (Organizational Characteristics)

One component of the data collection instrument is ground ambulance organization characteristics, which is information regarding the identity of the organization and respondent(s) service area, ownership, response time, and other characteristics (84 FR 62871 through 62875). One characteristic on which we sought information is organization type, including whether costs are shared with fire or police response or health care delivery operations (84 FR 62871). The instrument contains a number of questions that are relevant to the issue of shared costs.

Section 2, Question 7 asks ''Which category best describes your ground ambulance operation?'' and allows respondents to select one of the following options:

(a) Fire department-based; (b) Police or other public safety department-based (including all-hazards public safety organizations); (c) Government stand-alone emergency medical services (EMS) agency; (d) Hospital or other Medicare provider of services (such as skilled nursing facility); (e) Independent/proprietary organization primarily providing EMS services; (f) Independent/proprietary organization primarily providing non-emergency services; or (g) Other (please specify).

Section 2, Question 8 subsequently asks respondents answering a, b, or d to Question 7 to ''confirm that your ground ambulance operation shares operational costs, such as building space or personnel, with these other operations.''

Section 2, Question 9 asks ''Does your ground ambulance operation share any operational costs, such as building space or personnel, with one of the following,'' offering respondents the following options: (a) A fire department (not presented if the response to Section 2, Question 7 is ''a''); (b) A police or other public safety department (not presented if the response to Section 2, Question 7 is ''b''); (c) A hospital or other Medicare provider of services (such as a skilled nursing facility) (not presented if the response to Section 2, Question 7 is ''d''); (d) Another healthcare organization (excluding hospitals, skilled nursing facilities, or other Medicare provider of services); (e) Another healthcare organization (excluding hospitals, skilled nursing facilities, or other Medicare provider of services); (f) Other (specify).

Collectively, the purpose of these three questions is to collect information on whether a portion of organizations' costs and revenues may be related to services or operations other than providing ground ambulance services. When this occurs, ground ambulance organizations are presented with additional instructions specifying how they should report costs and revenues associated with providing ground ambulance services rather than these other services or operations.

Based on feedback from ground ambulance organizations, we believe the specific wording of Section 2, Question 9 may be confusing. The question asks respondents whether they share operational costs with ''one of the following,'' implying respondents are limited to a single response, even though in some cases respondents may wish to select multiple responses. Furthermore, ground ambulance organizations may have difficulty interpreting the phrase ''share any operational costs.'' We received questions from some ground ambulance organizations asking whether renting space from a fire department qualified as a ''shared operational cost.'' The intent of the question was to ask about shared ownership and accounting, not renting facility space, sharing a physical space with a separate organization, or similar business and logistical arrangements.

We propose to revise Section 2, Question 9, to read, ''Does your organization provide any of the following services or operations (select all that apply)?'' retaining the current response options. This change clarifies that the intent of Section 2, Question 9 is to collect information on services or operations provided by the sampled organization. We invite comments on our proposal regarding reporting shared services.

b. Proposed Change to Average Trip Time Question

We stated that the area served by ambulance organizations is an important characteristic and finalized a policy to collect information on the geographic area served by each ambulance organization in Section 3 of the data collection instrument (84 FR 62875). We included questions related to average trip time in primary and secondary service areas (questions 3 and 6 of Section 3) that were important to understand how geographic distance between the ground ambulance organization's facilities and patients affects costs (84 FR 62873).

Section 3 (Service Area), Questions 3 and 6 in the instrument ask ground ambulance organizations to report their ''average trip time'' using a set of categorical time ranges (for example, 30–60 minutes). These questions define average trip time as ''the time the ambulance leaves the station to when that ambulance is available to take another call.'' Based on feedback from ground ambulance organizations, we believe this definition may be confusing in cases where an ambulance responds to a call from a location other than the station (for example, while en route to another call, from a standby event, or from a hospital). Based on the literal wording of the question, it is not clear whether and if so, how ground ambulance organizations should report trip times for responses not originating at a station when responding to this question, leading to potentially missing or biased data.

We are proposing that this question be revised to ask for ''average time on task'' defined as ''from the time an ambulance begins its response to the time when the ambulance is available to respond to another call (that is, time on task)'' to better capture interfacility transfers and situations when an ambulance is already out and responds from a site other than the central station. We believe this change in the wording of the question would be clearer to respondents and would result in higher-quality reported data. We invite comments on our proposal to change the definition of the average trip time.

c. Proposed Change to Secondary Service Area Instructions

In Section 3, Question 4 instructions define the secondary service area for an organization as ''outside [its] primary service area, but one where [it] regularly provide[s] services through mutual or auto-aid arrangements. The instruction directs organizations to ''not include areas where [they] provide services only under exceptional circumstances.'' We were notified that some ground ambulance organizations are unsure how to report areas where they (a) did have mutual or auto-aid arrangements in place, which aligns with the definition of secondary service area in the instructions, but where (b) they responded to calls only very rarely, for example once a year, which could be considered an ''exceptional circumstance'' and ignored for reporting per the instruction.

Although the instructions leave the determination of whether an organization has a secondary service area at the discretion of the sampled ground ambulance organization, we believe that some organizations may benefit from a rule of thumb or example to help assess whether they should or should not report a ZIP code as being part of their secondary service area. We propose to add the following text to the Section 3, Question 4 instructions: ''Some, but not all, ground ambulance organizations regularly provide service outside of their primary service area, for example through mutual or auto-aid agreements with nearby municipalities. If this applies to your organization, please report areas that are outside your primary service area but where you regularly provide services as part of your secondary service area. You do not need to report areas where you provide services very rarely or only under exceptional circumstances (for example, when participating in coordinated national or state responses to disasters or mass casualty events). Use your judgment as to whether your organization regularly serves a secondary service area. For example, you may choose to consider ZIP codes outside your primary service area but where you had 5 or more responses during the data collection period as part of your secondary service area if you believe these transports have a significant impact on your organization's costs.'' Even with this added text, ground ambulance organizations could still determine whether they do or do not have a secondary service area for the purposes of reporting in the Medicare Ground Ambulance Data Collection System. We invite comments on our proposal to revise the secondary service area instructions.

d. Proposed Change to the 90th Percentile Emergency Response Time

Section 4 (Emergency Response Time), Question 3 asks ground ambulance organizations to report the

90th percentile emergency response time, which the question defines as the time separating the quickest 90 percent of responses from the longest 10 percent of responses. The intent of the question was to collect information to help CMS understand the difference between average response times and atypical ''outlier'' response time. In the CY 2020 PFS proposed rule (84 FR 40688), we proposed to include a question on average response time. As we noted in the CY 2020 PFS final rule (84 FR 62873), several commenters to the CY 2020 PFS proposed rule recommended asking ground ambulance organizations to provide 90th percentile response time rather than or in addition to the average response time. They believed 90th percentile response time is a more accurate indicator of ambulance services capabilities and quality. They stated that the average time has too wide a range for error, since roughly half of responses are quicker/slower than average. They further stated that using average response time also tends to flatten the data, which means the fastest and slowest organizations did not stand out as much. In response to these comments (84 FR 62874), we finalized an additional question to the instrument asking ground ambulance organizations responding to emergency calls for service to report their 90th percentile response time.

Based on feedback from ground ambulance organizations that we have received on this question since we finalized the instrument, we believe most ground ambulance organizations will find it challenging to interpret this question and report the requested information. Several ground ambulance organizations have indicated that they would misinterpret this question, describing a shorter 90th percentile emergency response time compared to average response time, which, while mathematically possible, is not the intent as we were interested in characterizing outlier emergency responses with unusually long response times.

Thus, we propose to revise the question to ask: ''what is your best estimate of the share of responses (enter percentage) that take more than twice as long as the average response time as reported in the prior question?'' We believe this would be an easier question for ground ambulance organizations to understand. The goal of this question is to help CMS understand whether the organization has some response times that are much longer than its typical response time. Although the question language would be different, the reported information would still help CMS understand the extent to which a small number of emergency responses may be substantially longer than the average response for each organization. We invite comments on our proposal to revise the question to ask respondents to report the share of responses with more than twice the average response time instead of their 90th percentile emergency response time.

e. Proposed Change to Reporting Paid Ambulance Transports

In the CY 2020 PFS final rule (84 FR 62876 through 62877), we established a series of questions in the data collection instrument to collect data on the volume and the mix of services, including paid ground ambulance transports, that is, ground ambulance transports where the ambulance provider or supplier was paid for a billed amount in part or in full. The general instructions for Section 5 (Ground Ambulance Service Volume) note: ''A paid ground ambulance transport refers to a ground ambulance transport for which your organization has been paid in full or in part by a payer and/or patient only. Depending on how your organization collects data, you may report (a) the number of transports furnished during the data collection period that were also paid during the data collection period, or (b) the number of transports paid during the data collection period even if some transports occurred prior to the data collection period.'' Furthermore, Section 5, Question 7 asks respondents, ''what was the total number of paid ground ambulance transports in calendar year 202X [or fill fiscal year as appropriate], across all payer types and regardless of the level of service or geography? (Enter number).''

Based on questions and feedback from ground ambulance organizations that we have received since we finalized the instrument, we believe respondents may have different interpretations of this question, which could lead to inconsistent reported data, including the reported total ground ambulance transports during the data collection period (Section 5, Question 6). The intent of this question was to capture the reported number of ground ambulance transports during the data collection period, provided such transports were paid by the time the information was prepared for reporting to CMS. We did not intend for organizations to report the total number of ground ambulance transports for which they received the payment itself during the data collection period.

We recognize that there is a temporal disconnect between when services are provided and when initial and final payment may be received. In order to standardize the information that is reported by all ground ambulance organizations, and to align the reported information on the number of responses and transports during the data collection period with information reported on the number of paid transports, we propose to clarify Section 5, Question 7 to ask ''Of the ground ambulance transports your organization provided in calendar year 202X [or fill fiscal year as appropriate], how many were paid (either in part or in full) across all payer types and regardless of the level of service or geography by the time you are reporting data to CMS?''

We recognize that the ''runout period,'' that is, the time from when services are provided to the time when data is being analyzed, will be short and variable across organizations, particularly for transports towards the end of organizations' data collection periods. Despite this limitation, we believe this approach is preferable to alternatives where (a) respondents have variable interpretations of Section 5, Question 7 and (b) where respondents are asked to report the number of transports for which payment was received during the data collection period, even if the transports for which payment was received happened prior to the data collection period. In the latter case, the number of paid ground ambulance transports could not be directly compared to the number of total ground ambulance transports reported in Section 5, Question 6.

We also are proposing to revise the general instructions in Section 5 to delete the following text as it will no longer be relevant: ''Depending on how your organization collects data, you may report (a) the number of transports furnished during the data collection period that were also paid during the data collection period, or (b) the number of transports paid during the data collection period even if some transports occurred prior to the data collection period.''

We invite comments on our proposal to revise reporting paid ground ambulance transports.

f. Proposed Change to Questions Related to Labor Hours

Section 7 (Labor Costs) of the data collection instrument asks respondents to report compensation and hours worked for ground ambulance staff. The instrument currently asks respondents to report, separately for each staff category: Total compensation, total hours worked inclusive of all responsibilities, and total hours worked unrelated to either ground ambulance or

public safety responsibilities. The rationale for asking for total compensation and hours, even if these include compensation and hours for activities other than those related to ground ambulance services, was to preserve the ability to compare compensation between organizations and to external benchmarks such as Bureau of Labor Statistics data. The last item, total hours worked unrelated to either ground ambulance or public safety responsibilities, can be subtracted from overall total hours worked related to ground ambulance and public safety responsibilities combined, and further allocation could separate ground ambulance time and compensation from public safety time and compensation for fire and other public safety-based ground ambulance organizations.

Based on questions received by ground ambulance organizations since we finalized the instrument and feedback through testing on Section 7 questions, we learned that some ground ambulance organizations may misinterpret the Section 7 questions. Specifically, we believe some organizations may assume the question is asking for hours ''related'' rather than ''unrelated'' to ground ambulance or public safety responsibilities given the focus of the data collection effort, despite instructions to the contrary. Relatedly, we were notified that some organizations were confused that the Section 7 questions did not provide an opportunity to report total hours worked related to ground ambulance responsibilities, which they assumed was an unintentional omission from the instrument.

We propose to change the instructions in Section 7 to ask respondents to report hours worked on different activities in such a way that the sum of hours worked across different activities equals total hours worked annually. We believe this approach would be easier for respondents to understand and estimate, resulting in less burden for respondents and higher quality reported information.

For stand-alone ground ambulance organizations, we propose to ask respondents to report each of the following per staff category: (a.) Total annual compensation; (b.) Total hours worked annually; (c.) Total hours worked annually related to ground ambulance operations; and (d.) Total hours worked annually related to all other responsibilities. With this change, the instructions in Section 7 would note that ''total hours worked annually related to ground ambulance operations'' plus ''total hours worked annually related to all other responsibilities'' should equal ''total hours worked annually.''

For fire department or other public safety-based ground ambulance organizations, we propose to ask respondents to report each of the following per staff category: (a.) Total annual compensation; (b.) Total hours worked annually; (c.) Total hours worked annually related to ground ambulance operations; (d.) Total hours worked annually related to fire, police, or other public safety operations; and (e.) Total hours worked annually related to all other responsibilities. The Section 7 instructions would note that the sum of total hours worked related to ground ambulance operations; fire, police, or other public safety operations; and all other responsibilities should equal total hours worked annually. We invite comments on our proposal to revise the labor hours.

g. Proposed Change to Instructions Related to Facility, Vehicle, and Equipment Certain Expenses

In the CY 2020 PFS final rule (84 FR 62882 through 62886), we finalized policies to collect cost information related to facilities, vehicles, and other equipment, consumables and supplies. The purpose of Sections 8 (Facilities Costs), 9 (Vehicles Costs), and 10 (Equipment, Consumable, and Supply Costs) in the instrument is to collect total expenses during the data collection period related to facilities, vehicles, and equipment and supplies, respectively. Based on feedback from ground ambulance organizations that we have received since we finalized the instrument, we are concerned that some respondents, particularly those that do not currently depreciate facilities, vehicles, and/or equipment for accounting purposes, may not be sure where to report some components of total expenses in these categories. Although we believe most ground ambulance organizations depreciate facilities, vehicles, and capital medical equipment, we were notified that some ground ambulance organizations do not depreciate these items in their regular accounting practices. Upon a review of the instrument, we found that the instructions and opportunities to report costs for organizations using a cash basis for accounting were inconsistent across Sections 8, 9, and 10 of the instrument. In some instances, ground ambulance organizations are asked to report annual depreciation expenses only, without a clear question related to expenses should the organization not regularly depreciate a certain category of asset. In other cases, there are questions asking respondents to report annual expenses other than annual depreciation expenses, but the instructions provide incomplete guidance on what expenses are in scope.

We considered several factors when developing our proposals to address these inconsistencies. Overall, the purpose of the questions in Sections 8, 9, and 10 is to collect comprehensive information on total expenses related to facilities, vehicles, and equipment and supplies during the organizations' data collection periods. We believe the primary purpose of changes and clarifications to questions in this section should be to ensure all expenses are reported from both organizations that do and do not depreciate facilities, vehicles, and equipment for accounting purposes. We understand that allowing organizations flexibility to report cost information using their current accounting approach will reduce burden. The instructions to the instrument currently state: ''In general, you will be able to report information collected under your organization's current accounting practices. We understand that some ground ambulance organizations use accrual-basis accounting while others use cash-basis accounting.'' We continue to believe this is the correct approach, and that alternatives would impose considerable additional burden on ground ambulance organizations.

We considered several broad alternatives on how to report facility, vehicle, and equipment expenses in Sections 8, 9, and 10. One option is to require all organizations to calculate and report depreciation for facilities, vehicles, and equipment using a standardized approach. Although this would increase burden for respondents, potentially significantly for organizations that do not currently calculate depreciation, it would result in the most standardized information being submitted to CMS and the fewest changes to the layout of the instrument. Another option would be to retain the current structure of the instrument but provide more detailed instructions on how organizations that do and do not depreciate facilities, vehicles, and equipment should report information. A third option is to add new screening questions to the instrument asking individually whether the organization depreciates facilities, vehicles, and equipment. The responses to these screening questions could be used to tailor the instructions, table headings, and question text later in the instrument to avoid confusion.

After considering these options, we propose to add screening questions to the instrument asking individually

whether the organization depreciates facilities, vehicles, and equipment. We believe this would not substantively affect response burden for organizations and may in some cases reduce burden by clarifying what and how information on expenses must be reported in Sections 8, 9, and 10.

There are two specific places in Sections 8 and 9 in the instrument where we believe the instructions on how to report annual expenses may not be clear. First, Section 8.2, Question 1 asks respondents to report annual expenses for each facility that they report as being related to their ground ambulance operation in Section 8.1, Question 3. Section 8.2, Question 1 is a table with columns for ''annual lease or rental costs,'' ''annual depreciation expenses,'' and ''annual mortgage, bond interest, and other costs of ownership.'' Although the instructions note ''do not report depreciation if your organization does not capitalize facilities for accounting purposes,'' it is not immediately clear where organizations that do not capitalize facilities should report expenses if the facility is owned outright (for example, in cases where a facility is acquired during the data collection period).

Second, Section 9.1, Question 5 and Section 9.2, Question 5 are tables where respondents report costs associated with individual vehicles. Both tables currently ask, ''What was the annual depreciation expense for this vehicle?'' Although the instructions note ''for owned vehicles, do not report depreciation if your organization accounts for vehicles on a cash basis,'' the instructions do not indicate where expenses for vehicles purchased during the data collection period should be reported by organizations that do not capitalize vehicles for accounting purposes.

We considered several options to clarify the instructions in Sections 8 and 9 specifically. One option is to preserve current table structures and item numbers in both sections while providing additional written instructions. We believe that although this will minimize disruption to the layout of the instrument, it will also do the least to address potential confusion around these questions. Another option is to add new columns in Sections 8 and 9 for facilities and vehicles purchased outright during the data collection period for organizations that do not depreciate these expenses. We propose to add an additional column for clarity, but note that if the screening questions are added as described above not all columns would appear for all respondents, particularly given our proposal to add screening questions related to reporting expenses in Sections 8 and 9.

We also believe there are specific instructions in Section 10 that may not be clear. Section 10.1, Question 1 and Section 10.2, Question 1 asks respondents to report ''annual depreciation expenses'' for medical and non-medical capital equipment, respectively. The Section 10 instructions note ''do not report depreciation if your organization uses a cash basis for accounting'' and that ''for capital expenditures, medical and non-medical equipment, most organizations will amortize costs over the life of the good'' but do not specify that organizations that do not depreciate medical or non-medical equipment should skip these questions and report expenses for equipment acquired during the data collection period in Section 10.1, Question 3, and Section 10.2, Question 3 instead.

We considered several options to clarify the instructions in Section 10 specifically. One option is to clarify in the instructions that organizations that do not depreciate medical or non-medical equipment should skip Section 10.1, Question 1 and Section 10.2, Question 1 and report expenses for equipment acquired during the data collection period in Section 10.1, Question 3, and Section 10.2, Question 3 instead. Although this would involve the least change to the instrument, we would lose the ability to distinguish between expenses for the kinds of equipment that most ground ambulance organizations depreciate for organizations reporting in this way. Another option is to change the instructions for Section 10.1, Question 1 and Section 10.2, Question 1 to refer to broad types of equipment that are typically considered capital medical and non-medical equipment, and then ask respondents to report relevant annual expenses for qualifying equipment in these questions, regardless of whether the expenses are annual depreciation expenses or purchase costs (for organizations not calculating depreciation). We propose to ask organizations that do not depreciate equipment to report expenses associated with purchasing equipment in Section 10.1, Question 1 and Section 10.2, Question 1. This option would preserve our and MedPAC's ability to separately analyze these expenses. We invite comment on these alternatives to address instructions related to facility, vehicle, and equipment expenses.

h. Proposed Changes to Questions Related to National Provider Identifier's (NPIs) Under Broader Parent Organizations

Some ground ambulance NPIs are part of broader parent organization companies that own and/or operate multiple ground ambulance NPIs. Section 2, Question 2 asks, ''Did your organization use more than one NPI to bill Medicare for ground ambulance services during the data collection period?'' Based on feedback from ground ambulance organizations that we have received since we finalized the instrument, we were notified that the use of ''organization'' in this question is potentially confusing because it is not clear whether the term applies to the organization sampled to report information to the Medicare Ground Ambulance Data Collection System (which, by definition, is an individual NPI) or to a broader ''parent organization.'' We propose clarifying the question to ask ''Is this NPI part of a larger 'parent organization' that owns or operates multiple NPIs billing for ground ambulance services?'' We are also proposing to clarify the wording of the follow-up instruction for organizations that answer ''yes'' to this question. The follow-up instruction currently reads, ''You are being asked to complete this instrument and enter data only for the following NPI: [pre-populate number].'' Because very large parent organizations may have several NPIs sampled and a single or small number of staff collecting and reporting data for multiple NPIs, we are proposing to revise the text to read, ''You are being asked to complete this instrument and enter data separately for each sampled NPI. The following questions refer only to the following NPI: [pre-populate number].''

The instrument asks these organizations to report an allocated share of parent organization expenses at the end of most sections of the instrument. For example, Question 3 in Section 7.2 on paid administration, facilities, and medical director staff costs asks, ''Please report the allocated portion of administrative labor costs incurred at the level of the parent organization/central office of this NPI based on your organization's approach for allocating costs to specific NPIs. (Enter dollar amount.)''

There are four sections in the instrument that lack similar questions: Section 7.1 (Paid EMT/Response Staff Compensation and Hours Worked), Section 7.3 (Volunteer Labor), Section 9.1 (Ground Ambulance Vehicle Costs), and Section 10.1 (Medical Equipment/

Supplies). Without these questions, total reported costs may be biased downward for NPIs that are part of broader parent organizations. We propose to add questions like the one reproduced above to the end of these four sections for completeness. The text would be the same as the above except for replacing ''EMT/response staff labor costs,'' ''costs associated with volunteer labor,'' ''ground ambulance vehicle costs,'' and ''medical equipment and supply costs'' for ''administrative labor costs'' in the respective sections.

Relatedly, for completeness, we propose to clarify in the instructions for Section 12 (Total Cost), Question 1, that organizations part of broader parent organizations should include an allocated portion of parent organization (or ''central office'') costs when reporting their total costs in this question. We invite comments on our proposal to address questions related to NPIs under broader parent organizations.

i. Other Clarifications to the Medicare Ground Ambulance Data Collection Instrument

We propose the following 11 additional clarifications and updates to the instrument:

i. Replacing all first-person language (for example, ''we'') with third-person language (for example, ''CMS'') throughout the instrument for editorial consistency.

ii. Section 2, Question 17: There is a typo where this question referred to itself rather than, as is implied by the ordering and framing of the question, the prior item. The question currently asks, ''other than what was reported in item 17 . . .,'' when it should read, ''other than what was reported in item 16 . . .''.

iii. Section 3, Question 2: This question currently asks, ''are you the primary emergency ambulance provider . . .,'' using ''provider'' more colloquially than elsewhere in the instrument where the same word is sometimes used to differentiate between Medicare providers of service and Medicare suppliers. We propose to reword this question to read, ''are you the primary emergency ambulance organization . . .''

iv. Section 4, Questions 1 and 2 Clarification: The question currently defines response time as ''the time from when the call comes in to when the ambulance or another EMS response vehicle arrives on the scene.'' We propose clarifying this definition to say ''the time from when the call comes in to dispatch to when the ambulance or another EMS response vehicle arrives on the scene.'' Relatedly, for Section 4, Question 2, we propose adding a second answer option for this question that reads, ''From the time our organization receives a call from dispatch to the time the ambulance or other EMS vehicle is at the scene.'' Respondents would still have the option to write-in their own response in Section 4, Question 2, if neither of the pre-programmed options apply to their organization.

v. Section 5, Question 3a. Clarification: This question asks respondents to report the percentage of ground ambulance responses that involve a non-transporting agency and the percentage of ground ambulance transports in which the non-transporting agency continues to provide medical care in the ambulance during a transport. Based on feedback from ground ambulance organizations that we have received since we finalized the instrument, we believe many organizations do not currently track this data and will not easily be able to begin tracking it. We propose clarifying this question to note that estimated percentages are acceptable, as they are in response to certain other questions in the instrument (where noted). We specifically propose to edit Section 5 question 3a. to read: ''What is your best estimate of the percentage of total ground ambulance responses that involved a non-transporting agency? (Enter percentage)''

vi. Section 7.1 Instruction Clarification: We propose clarifying ''You will report on these staff in a different section'' to ''You will report on these staff in a later section'' to make it clear that the opportunity to report on these staff follows the current instruction.

vii. Sections 7.1 and 7.2 Instruction Clarification: We propose to add ''employer payroll taxes'' as an additional example of a component contributing to total compensation, without altering any of the definitions or other instructions in these sections.

viii. Section 7.2, Question 3 Clarification: We propose adding a clarification warning for respondents not to consider labor that was reported elsewhere when responding to this question.

ix. Section 7.3, Question 4 Clarification: We propose adding a clarification that medical director volunteer hours do not contribute to this response and a reminder that they are reported separately below (Section 7.3, Question 5).

x. Section 10 Instructions: We propose to correct a typo in the instructions where the instrument describes ''operation expenses'' rather than ''operating expenses'' as intended.

xi. Section 13, Question 3 Clarification: Based on the instructions for this question, organizations may report revenue from specific payers that include patient cost-sharing amounts. To ensure patient cost-sharing is not reported twice, we recommend clarifying the item in the chart that currently reads, ''Patient self-pay (amount patients pay for deductibles, coinsurance, etc.) to read, ''Patient self-pay (cash payment and the amount patients paid for deductibles, coinsurance, and other cost-sharing only if not reported in a row above.)'' We invite comments on these proposed clarifications and updates to the instrument.

4. Collection and Reporting of Information Under the Data Collection System

In the CY 2020 PFS final rule (84 FR 62893), we finalized our sampling proposals to implement a 25 percent stratified sample in each of the first four years of data collection and codified the representative sample approach at § 414.626(c). CMS' sampling approach is designed to result in representative samples of ground ambulance organizations in terms of key characteristics including provider versus supplier status, service area population density, volume of transports, and ownership category. The selected ground ambulance organizations for year 1 and year 2 have already been listed on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html.*

In the CY 2020 PFS final rule (84 FR 62894), we finalized the data collection period as a continuous 12-month period of time, which is either the calendar year aligning with the data collection year, or the organization's annual accounting period that begins during the data collection year when an organization has an annual accounting period (such as a fiscal year) that differs from the calendar year and the organization elects to collect and report data over this period rather than the calendar year. We also finalized our proposal to require organizations to report data during a 5-month data reporting period starting immediately following the end of the data collection period. The data collection and reporting requirements for selected ground ambulance organizations were codified at § 414.626(b).

As part of the Medicare Ground Ambulance Data Collection System, sampled ground ambulance

organizations will report information to CMS using a web-based version of a data collection instrument that is posted on the CMS website at *https://www.cms.gov/Center/Provider-Type/Ambulances-Services-Center.html*. We are currently developing the Medicare Ground Ambulance Data Collection System and stated in the CY 2020 PFS final rule (84 FR 62867) that the web-based survey would be available before the start of the first data reporting period to allow time for users to register, receive their secure login information, and receive training from CMS on how to use the system.

Due to the COVID–19 public health emergency (PHE), we issued two blanket waivers (May 5, 2020 and November 25, 2020) to delay the data collection and data reporting periods under the Medicare Ground Ambulance Data Collection System. The first waiver delayed the data collection period and data reporting period for selected year 1 ground ambulance organizations and the second waiver delayed the data collection periods and data reporting periods for selected year 1 and year 2 ground ambulance organizations.

This revised modification has been issued on page 32 in the following document: *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*. Specifically, we modified the data collection period and data reporting period, as defined at § 414.626(a), for ground ambulance organizations (as defined at § 414.605) that were selected by CMS under § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) and for ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at § 414.626.

Under this modification, these ground ambulance organizations would select a new continuous 12-month data collection period (organizations may choose a collection period aligning with the calendar year or the organization's fiscal year) that begins between January 1, 2022 and December 31, 2022, to collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument during their selected data collection period, and submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. We modified this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020–2021 so that they can focus on their operations and patient care during the COVID–19 public health emergency (PHE). We stated, when the blanket waiver was granted, in the COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document (page 63 of this document: *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*) that CMS will not allow an option to continue with their current data collection period because the data collected in 2020 and 2021 during the PHE may not be reflective of typical costs and revenues associated with providing ground ambulance services.

As a result of the COVID–19 delay, ground ambulance organizations selected in year 1, 2, and 3 will have the same data collection periods beginning between January 1, 2022 and December 31, 2022 and will have the same data reporting periods beginning between January 1, 2023 and December 31, 2023. In the CY 2020 PFS final rule (84 FR 62893), we finalized our sampling proposals to implement a 25 percent stratified sample in each of the 4 years of data collection. Prior to the delay, we anticipated approximately equal shares of ground ambulance organizations would collect and report data in four consecutive periods. However, as a result of the delays, there will now be approximately 75 percent of the ground ambulance organizations that will have data collection periods that start in the same year and subsequently will have data reporting periods starting in the same year. Later, a final 25 percent sample of ground ambulance organizations in year 4 will collect and report data.

When finalizing our policies in regard to ground ambulance collection and reporting of data, we did not intend to have approximately 75 percent of ground ambulance organizations collect and report data at the same time. To provide MedPAC with the data needed for analysis, acknowledging that due to the COVID–19 delay there will be a delay in CMS providing that data, we believe that we should revise the data collection period and data reporting period for selected ground ambulance organizations in year 3.

Accordingly, we are proposing to revise the data collection period beginning between January 1, 2022 and December 31, 2022 and data reporting period beginning between January 1, 2023 and December 31, 2023 for selected ground ambulance organizations in year 3. Under this proposal, there will be a new data collection period beginning between January 1, 2023 and December 31, 2023 and a new reporting period beginning between January 1, 2024 and December 31, 2024 for selected ground ambulance organizations in year 3. With this proposal, we plan to do the sample in 2022 for selected ground ambulance organizations in year 3 rather than the current plan in 2021. The main advantage of delaying the year 3 sample is that the selected organizations would be more representative of the organizations actually collecting beginning in 2023 and reporting beginning in 2024. The longer the delay between sampling and the data collection and data reporting, the more changes in the industry (for example, NPIs ceasing ground ambulance or all operations). This timeline would align with the data collection period and data reporting period requirements for selected ground ambulance organizations in year 4. As a result, there would be approximately 50 percent of ground ambulance organizations selected in year 1 and 2 with data reporting periods beginning between January 1, 2023 and December 31, 2023 and approximately 50 percent of ground ambulance organizations selected in year 3 and 4 with data reporting periods beginning between January 1, 2024 and December 31, 2024.

Due to the delay caused by the COVID–19 PHE, we examined the possibility of extending the data reporting to encompass 4 years as planned instead of 2 years. We concluded that it would not be feasible to extend the data reporting period over 4 years. Extending the data reporting to encompass four years would further delay MedPAC receiving the data required to analyze for its report to Congress, which is required to be submitted by March 15, 2023. The sampling for year 1 and year 2 selected ground ambulance organizations has already been completed and the lists for the selected ground ambulance organizations in year 1 and year 2 are posted on the CMS website.

With this proposal, more data would be collected in 2023 as there would hopefully be more distance from the peak of the COVID–19 pandemic. Thus, it is our hope that 2023 will be even more reflective of a typical year of costs for ground ambulance organizations than 2022. As the course of the pandemic continues to evolve, we believe that our proposal provides a potential for more even distribution of data over two years for comparison by MedPAC. We invite comments on our proposal to revise the data collection period and data reporting period for

ground ambulance organizations selected in year 3.

5. Proposed Change to the Notification Process for Selected Ground Ambulance Organizations Required To Report

In the CY 2020 PFS final rule, we codified our notification process at § 414.626(c)(3) and (b)(1). We stated at § 414.626(c)(3) that CMS will notify an eligible ground ambulance organization that it has been selected to report data for a year at least 30 days prior to the beginning of the calendar year in which the ground ambulance organization must begin to collect data by posting a list of selected organizations on the CMS web page and providing written notification to each selected ground ambulance organization via email or U.S. mail.

The Medicare Administrative Contractor (MAC) is responsible for providing written notifications to the selected ground ambulance organizations in their service area. We codified their role at § 414.626(b)(1) which states that within 30 days of the date we notify a ground ambulance organization that it has been selected to report data under this section, the ground ambulance must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to the ground ambulance organization's Medicare Administrative Contractor.

We propose to make a technical revision to § 414.626(b)(1) to state that the selected ground ambulance organization provide the start date of the data collection period to CMS or its contractor instead of the Medicare Administrator Contractor. This change will provide CMS with flexibility to have the MACs or other contracted entities provide written notifications and collect information from the selected ground ambulance organizations. If we find the response rate is low, having the flexibility to contract with other entities that could employ additional outreach resources may be useful. This revision would not preclude CMS from including the MACs in the notification process. We also propose to correct a typographical error at § 414.626(b)(1), which currently states ''a ground ambulance must select a data collection period'' to read ''a ground ambulance organization must select a data collection period.'' We invite comments on our technical revisions to the citation at § 414.626(b)(1).

6. Payment Reduction for Failure To Report

Section 1834(l)(17)(D)(i) of the Act requires that beginning January 1, 2022, subject to clause (ii), the Secretary reduce the payments made to a ground ambulance organizations under section 1834(l)(17) of the Act for the applicable period by 10 percent if the ground ambulance organization is required to submit data under the data collection system with respect to a data collection period under the data collection period and does not sufficiently submit such data.

We stated in the CY 2020 PFS final rule (84 FR 62895) that we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than the date that is 3 months following the date that the ground ambulance organization's data reporting period ends. In this final rule, we provided examples of when the determination will be made based on calendar year and fiscal year data collection period beginning in 2020. Due to the delay caused by the COVID–19 PHE, we did not receive data collected in 2020. We will begin to follow this timeline to make a determination that the ground ambulance organization is subject to the 10 percent payment reduction when data collected in 2022 is required to be reported in 2023 for selected ground ambulance organizations in year 1 and year 2.

For example, if a selected ground ambulance organization's data collection period is based on a calendar year, that is, January 1, 2022 through December 31, 2022, we will allow a ground ambulance organization 5 months to report the data collected during the data collection period. For this example, the data reporting period for this organization is January 1, 2023–May 31, 2023. We would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than August 31, 2023. With this timeframe, we would apply the 10 percent reduction in payments, if applicable (no hardship exemption or informal review is granted), for ambulance services provided between January 1, 2024 and December 31, 2024.

As another example, if a selected ground ambulance organization's data collection period is based on a fiscal year, that is, October 1, 2022 through September 30, 2023, we will allow a ground ambulance organization 5 months to report the data collected during the data collection period. For this example, the data reporting period for this organization is October 1, 2023 –February 28, 2024, we would make a determination that the ground ambulance organization is subject to the 10 percent payment reduction no later than June 1, 2024. With this timeframe, we would apply the 10 percent reduction in payments, if applicable (no hardship exemption or informal review is granted), for ambulance services provided between January 1, 2025 and December 31, 2025.

7. Public Availability of Data

We stated in the CY 2020 PFS final rule (84 FR 62897), the data will be made available to the public through posting on our website at least every 2 years and we will post the summary results by the last quarter of 2022. We codified the public availability at § 414.626(f), which states: (f) Public availability of data. Beginning in 2022, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

Due to the COVID–19 delay, we are proposing to revise § 414.626(f) to state that we will make the data collected under § 414.626 publicly available beginning in 2024. We invite comments on our proposal to revise the timeline when the public availability of data will begin.

L. Medicare Diabetes Prevention Program (MDPP)

The Medicare Diabetes Prevention Program (MDPP) expanded model is a structured intervention that aims to prevent or delay onset of type 2 diabetes among eligible Medicare beneficiaries diagnosed with pre-diabetes. The MDPP expanded model is an expansion of duration and scope of the Diabetes Prevention Program (DPP) model test, which was initially tested through a Round One Health Care Innovation Award. MDPP services are furnished in community and health care settings by organizations that enroll in Medicare as MDPP suppliers, a new supplier type, even if they have an existing Medicare enrollment as another supplier type. MDPP services furnished under the MDPP expanded model are covered as an additional preventive service with no cost-sharing under Medicare. Eligible organizations seeking to furnish MDPP services began enrolling in Medicare as MDPP suppliers on January 1, 2018, and began furnishing MDPP services on April 1, 2018.

We propose to amend our regulation at § 410.79 to preclude the provision of ongoing maintenance sessions unless

the MDPP beneficiary has started his or her first core session on or before December 31, 2021. In addition, we propose to amend § 414.84(b) and (c) to update the amount of the performance payments for the core sessions and core maintenance sessions and ongoing maintenance sessions (where applicable) to be consistent with the proposal herein. We propose that this change apply to all MDPP beneficiaries starting the MDPP set of services on or after January 1, 2022. Additionally, we propose to amend § 424.205(b) to add a provision to waive the provider enrollment Medicare application fee for all organizations enrolling in Medicare as MDPP suppliers that submit an application on or after January 1, 2022. Finally, we propose to make a conforming amendment to § 424.502 to remove a reference to the CMS–20134 from the definition of ''institutional provider.'' (In accordance with § 424.514, institutional providers generally must pay the enrollment application fee.)

We do not anticipate that the proposed changes would impact our ability to complete an evaluation of the MDPP expanded model, but the evaluation would consider these proposed changes if enacted. The evaluation would continue to use beneficiary-level Diabetes Prevention Recognition Program (DPRP) encounter data and program data furnished by the CDC in combination with Medicare claims data to analyze the long-term utilization of services by beneficiaries who have received the MDPP set of services. We would use these data as planned to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending. We anticipate that these programmatic adjustments are likely to result in more MDPP suppliers, increased beneficiary access to MDPP services and an ongoing reduction of the incidence of diabetes in eligible Medicare beneficiaries, in both urban and rural communities.

1. Proposed Changes to § 410.79(b), (c), and (e)

We are proposing to amend certain MDPP expanded model policies previously finalized in the CY 2017 PFS final rule (81 FR 80459 through 80475 and 80552 through 80558), the CY 2018 PFS final rule (82 FR 34157 through 34158), and the CY 2021 PFS final rule 85 FR 50074). Previous rules established policies related to the set of MDPP services, beneficiary eligibility criteria, reimbursement structure, and supplier enrollment requirements and compliance standards.

MDPP has experienced challenges recruiting suppliers to participate in the expanded model, which has limited beneficiary access to the preventive services offered under the expanded model. Existing and prospective suppliers have reported that the length of the set of MDPP services and the payment timing and amounts have made implementation and operation of MDPP burdensome and has hindered participation. Currently, MDPP suppliers are required to offer up to 2 years of MDPP services to eligible MDPP beneficiaries. The MDPP set of services, as defined in § 410.79(b), consists of at least 16 sessions offered during the core sessions phase (Months 1–6), monthly maintenance sessions offered during the core maintenance sessions phase (Months 7–12) (collectively the ''core sessions phase''), and additional monthly sessions offered during the ongoing maintenance sessions phase (Months 13–24) for eligible beneficiaries. To be eligible for the ongoing maintenance sessions phase, a beneficiary must meet the minimum weight-loss requirement (5 percent weight loss from baseline), as defined in § 410.79(b), and maintain the minimum weight-loss requirement on a quarterly basis to continue to receive MDPP services in subsequent quarters. The ongoing maintenance sessions delivered in year 2 are a unique feature of MDPP. Both the CMS-funded Health Care Innovation Award (HCIA) to the Young Men's Christians Association (YMCA) of the USA (Y–USA), referred to as the DPP model test hereafter, and the CDC's National Diabetes Prevention Program (National DPP) was/are 12 months in length.

CMS included the ongoing maintenance sessions phase in the MDPP set of services to support participants in solidifying the behavioral changes that resulted in weight loss during the first 12 months. In the CY 2017 PFS proposed rule, we proposed adding the ongoing maintenance sessions phase to follow the completion of the 12-month core sessions phase if the beneficiary achieved and maintained the required minimum weight loss of 5 percent from the baseline weight. The proposed rule did not place a limit on the number of ongoing maintenance session phases an eligible beneficiary could attend. In response to stakeholder comments, we modified the proposed policy to limit access to up to 2 years of ongoing maintenance sessions after the 12-month core sessions phase. In the CY 2018 PFS, we again modified the policy to limit access to ongoing maintenance sessions to 1 year after the 12-month core sessions phase as long as MDPP beneficiaries maintained the 5 percent weight loss.

Despite limiting the ongoing maintenance sessions phase to 1 year, we have heard that the MDPP suppliers find the implementation, operation, and costs of the ongoing maintenance sessions phase burdensome. We anticipate that these proposed changes would improve the uptake of organizations enrolling in Medicare to become MDPP suppliers, thus enabling more beneficiaries to access the MDPP set of services. Collectively, this would improve CMS's ability to evaluate the MDPP expanded model as more suppliers and beneficiaries participate in the expanded model test. Currently, more than 1,000 organizations nationally are eligible to become MDPP suppliers based on their preliminary or full CDC DPRP status. However, only 27 percent of eligible organizations are participating in MDPP. Based on an analysis of National Health and Nutrition Examination Survey (NHANES) data, an estimated 16.4 million people are eligible for MDPP; [116] to date, over 3,600 beneficiaries are participating in the MDPP set of services. We anticipate that the removal of the second year of the MDPP set of services on a prospective basis would make MDPP attractive to more MDPP eligible organizations and beneficiaries.

The requirement to offer a second year of the MDPP set of services has also caused confusion among MDPP suppliers because it is inconsistent with the CDC National DPP requirements and curriculum. Because there is no defined curriculum for the ongoing maintenance sessions phase, MDPP suppliers repeat parts of the curriculum they previously used during the core sessions phase per CDC guidance and their updated 2021 DPRP Standards.[117] We have heard anecdotally, through written inquiries and questions asked by MDPP suppliers during MDPP educational events, that MDPP suppliers struggle with discerning the appropriate timing of determining whether a beneficiary has met and/or maintained the 5 percent minimum weight-loss requirement necessary for continued eligibility for and during the ongoing maintenance

[116] Lee AK, Warren B, Liu C, Foti K Selvin E (2019) Number and Characteristics of US Adults Meeting Prediabetes Criteria for Diabetes Prevention Programs: NHANES 2007–2016, J Gen Intern Med 34(8):1400–2. *https://link.springer.com/content/pdf/10.1007/s11606-019-04915-w.pdf.*

[117] CDC DPRP Standards (March 1, 2021) *https://nationaldppcsc.cdc.gov/s/article/DPRP-Standards-and-Operating-Procedures.*

sessions phase. To be eligible to continue to the ongoing maintenance phase of MDPP, beneficiaries must lose and/or maintain a 5 percent weight loss from baseline. MDPP suppliers are responsible for determining if a MDPP beneficiary has met and/or maintained the 5 percent weight loss from baseline during the applicable session and phase. A supplier must submit a claim to the Medicare Administrative Contractor (MAC) for the 5 percent weight loss achievement for each beneficiary, otherwise, all subsequent ongoing maintenance session claims may be rejected by the MAC. Suppliers have 12 months from the date of service to submit claims, if they delay the claim submission for the 5 percent weight loss performance goal, this may impact a supplier's ability to get paid for the ongoing maintenance sessions. For example, if a beneficiary achieves the 5 percent weight loss goal during the first 6 months of MDPP, or during the core services period, and they do not submit the claim for the 5 percent weight loss goal until after the ongoing maintenance interval has started, the supplier risks having their claim for the ongoing maintenance interval rejected. Furthermore, in this scenario, the supplier will need to submit a claim for the second core maintenance session interval with a 5 percent weight loss for the beneficiary to continue with ongoing maintenance sessions. MDPP monitoring data suggest that 82 percent of MDPP beneficiaries for whom we have claims for the 5 percent weight loss goal achievement reach that goal in the first 6 months of the expanded model. However, our monitoring data show claims for MDPP ongoing maintenance sessions for only 10 percent of MDPP beneficiaries and that beneficiary attendance sharply drops after the first quarter of the initial core session. Collectively, these data suggest that suppliers may not be incentivized to retain MDPP beneficiaries after they attend the 9th core session in the set of MDPP services, which MDPP beneficiaries likely reach during the first quarter of the expanded model, or after the MDPP beneficiary has achieved the 5 percent weight loss milestone.

Existing MDPP suppliers report frustration with the requirements associated with the ongoing maintenance phase and we believe that the additional burden and cost of providing the ongoing maintenance sessions is a deterrent to prospective MDPP suppliers. Organizations have communicated to CMS their difficulties in keeping MDPP beneficiaries engaged in the expanded model. For an example, suppliers are reimbursed after they successfully submit claims for beneficiary attendance, after the 1st, 4th, and 9th core sessions during the first 6 months of the MDPP set of services, and then if beneficiaries attend 2 monthly sessions per quarter thereafter. MDPP eligible organizations have cited beneficiary acquisition and retention as a leading barrier to their MDPP supplier enrollment. Stakeholders and suppliers have commented that the payment levels for a second year are inadequate to cover supplier costs given the low volume of beneficiaries who participate in the ongoing maintenance phase and drive up the per-beneficiary costs for the supplier. Stakeholders comment that sessions have the same fixed costs, yet there are a diminishing number of MDPP beneficiaries eligible to participate. As previously noted, our fee-for-service claims-based monitoring data show that only approximately 10 percent of MDPP beneficiaries continue with the ongoing maintenance sessions phase and the majority of MDPP beneficiaries achieve the 5 percent weight loss milestone within the first 6 months of the MDPP set of services. Given our data, stakeholder comments, the lack of the ongoing maintenance year alignment with the CDC's National DPP and the DPP model test, the ongoing maintenance phase is not sufficiently beneficial to continue requiring and may be causing harm to the expanded model's overall goals.

As such, we are proposing to amend our regulations to preclude coverage of ongoing maintenance sessions unless the MDPP beneficiary has started his or her first core session on or before December 31, 2021. Specifically, we propose to amend § 410.79(c)(1)(ii) to provide that an MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary started his or her first core session on or before December 31, 2021. If adopted, this change would effectively make the MDPP timeframe consistent with the National DPP for MDPP service periods that begin on or after January 1, 2022. In addition, if finalized, this policy would reduce the administrative burden and costs associated with the ongoing maintenance sessions phase to MDPP suppliers with minimal impact to beneficiaries given their historically low participation rate in the second year of MDPP. This proposed change is consistent with the authority in section 1115A(c) of the Act, and we anticipate this change would improve our ability to evaluate the expanded model test due to an anticipated increase in supplier enrollment, which will increase beneficiary access to the expanded model.

In conjunction with the proposed change to remove the ongoing maintenance sessions phase from the MDPP services period, we are proposing to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments to address stakeholder concerns that the current MDPP payment structure does not cover reasonable costs of MDPP suppliers to deliver the MDPP set of services. For example, the proposed attendance-based performance payments are based on a standardized per-session rate, paid after the 1st, 4th, and 9th sessions attended during the core sessions intervals, and after attending the two (2) sessions during each of the core maintenance intervals. We propose to increase performance payments for MDPP beneficiary achievement of the 5 percent weight loss goal, as well as continued attendance during each core maintenance interval. Although the proposed maximum payment of $661.00 over a 1-year service period is less than the current maximum payment of $704.00 under the original 2-year payment structure, we believe the proposed payment structure would have a net positive effect on the MDPP suppliers. Additionally, the maximum proposed payment is more than the 2021 National Average Facility Medicare Payment of $528.00 for the face-to-face intensive behavioral counseling for obesity (IBT-Obesity) for individuals.[118] The IBT-Obesity, a Medicare preventive service benefit whose goal is to promote sustained weight loss among Medicare beneficiaries with a BMI of 30 kg/m2 and higher, pays a similar per session rate as what we are proposing for MDPP, including a maximum of 22 IBT-Obesity sessions in a primary care setting over a 12-month period. Our Office of the Actuary estimated that that the average payment for an MDPP supplier would increase by $100 with the elimination of the second year of MDPP. While the proposed maximum payment available to an MDPP supplier would decrease when compared to the maximum payment under the original 2-year payment structure, the second year of the MDPP set of services have historically been far less utilized than first year set of services. Therefore, it is anticipated that eliminating the second year of payments would have minimal negative impact on the expanded model's costs. Table 28 shows the

current 2021 non-cumulative performance payments and the proposed performance payments for those MDPP beneficiaries who started their first core service on or after January 1, 2022. We are not proposing to change the payment rates for ongoing maintenance sessions in cases where a beneficiary remains eligible for them (that is, because they started receiving the MDPP set of services on or before December 31, 2021 and achieve the minimum required weight loss); rather, we proposed to maintain those payment rates until such time as ongoing maintenance sessions are phased out.

TABLE 28: MDPP Payment Structure

Payment Description	Current	Proposed
Core Sessions (Months 1-6)		
Attend 1 Core Session or Bridge Payment	$26	$26
Attend 4 Core Sessions	$52	$78
Attend 9 Core Sessions	$95	$130
Core Maintenance (CM) Sessions (Months 7-12)		
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 1 (Months 7-9)	$15	$52
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 1 (Months 7-9)	$63	$106
Attend 2 Core Maintenance Sessions (No 5% WL) in CM Interval 2 (Months 10-12)	$15	$52
Attend 2 Core Maintenance Sessions (5% WL) in CM Interval 2 (Months 10-12)	$63	$106
5% WL Achieved from baseline weight	$169	$189
9% WL Achieved from baseline weight	$26	$26
Ongoing Maintenance Sessions (Months 13-24)		
Attend 2 Ongoing Maintenance (OM) Sessions in OM Interval 1 (Months 13-15)	$52	
Attend 2 Ongoing Maintenance Sessions in OM Interval 2 (Months 16-18)	$52	
Attend 2 Ongoing Maintenance Sessions in OM Interval 3 (Months 19-21)	$53	
Attend 2 Ongoing Maintenance Sessions in OM Interval 4 (Months (22-24)	$53	
Total Maximum Payment*	**$704**	**$661**

Our data from the DPP model test showed beneficiaries who finished at least nine (9) sessions of the model were considered ''completers'' and had better weight loss and lower Medicare spending than non-completers (those who attended fewer than 9 sessions). The DPP model test showed that beneficiaries who attend nine or more sessions will, on average, experience a 6.24 percentage point increase in weight loss compared to beneficiaries attending fewer than nine sessions. Currently, our payment structure does not pay for per session attendance, and stakeholders have commented that the expanded model, in its current state, is creating inequities in access to MDPP among eligible beneficiaries because suppliers cannot invest in the costs to retain beneficiaries who may have access barriers related to transportation or distance of the MDPP location from their home. We anticipate the proposed changes to the payment structure, which would pay a total of $61 more per beneficiary who attends at least 9 session than what is currently paid, would encourage existing suppliers to retain MDPP beneficiaries given the one-year commitment versus two for the MDPP set of services. Continuous beneficiary attendance is critical to reaching key outcomes such as 5 percent weight loss and reduced Medicare spending. Additionally, we expect more eligible organizations will enroll as MDPP suppliers due to our eliminating the ongoing maintenance period, increasing the number of locations beneficiaries may access the MDPP set of services. We expect the proposed changes to the MDPP payment structure would not affect MDPP's qualification for expansion. We would use the CDC DPRP and MDPP claims data as planned to assess whether the MDPP expanded model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending. We anticipate that these programmatic adjustments are likely to result in more MDPP suppliers, increased beneficiary access to MDPP services and an ongoing reduction of the incidence of diabetes in eligible Medicare beneficiaries, in both urban and rural communities.

In our regulatory impact analysis, the CMS Office of the Actuary estimates that these proposed changes would reduce Medicare spending over 10 years, with potential savings starting in 2026. Increasing the first-year payment amounts to suppliers and waiving the Medicare enrollment fee (as discussed below) should increase access to MDPP, resulting in more utilization of the MDPP set of services.

We are proposing a change to our emergency policy at § 410.79(e)(3)(v)(C) to account for the proposed elimination of ongoing maintenance sessions for MDPP beneficiaries who start the set of MDPP services on or after January 1, 2022. Under this proposal, only beneficiaries who start the MDPP set of services between January 1, 2021, and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event may either resume or restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event if they elect not to continue with MDPP services virtually during the applicable 1135 waiver event.

As noted above, we propose to remove the ongoing maintenance sessions phase for all MDPP beneficiaries who start MDPP set of services on or after January 1, 2022. MDPP beneficiaries who start the MDPP

set of services on or before December 31, 2021 would be able to continue with the ongoing maintenance phase if they meet the eligibility requirements described in § 410.79(c)(3). Table 29 summarizes our proposal for the MDPP services period based on beneficiary start date.

TABLE 29: Summary of the MDPP Services Period Based on Beneficiary Start Date

Beneficiary MDPP Status	MDPP Services Period
Beneficiary starts MDPP set of services on or before December 31, 2021	• Core Services Period, which is the first 12 months of the MDPP services period, and consists of: (A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and (B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period. • Ongoing Maintenance Services Period, consists of up to four 3-month ongoing maintenance session intervals offered during months 13 through 24 of the MDPP services period
Beneficiary starts MDPP set of services on or after January 1, 2022	• Core Services Period, which is the first 12 months of the MDPP services period, and consists of: (A) At least 16 core sessions offered at least one week apart during months 1 through 6 of the MDPP services period; and (B) Two 3-month core maintenance session intervals offered during months 7 through 12 of the MDPP services period.

Additionally, we propose to remove the second duplicate paragraph (c)(3)(ii) given that the electronic CFR contains two paragraphs (c)(3)(ii), both containing the exact same language.

We are proposing to amend our regulation at § 410.79(b), (c), and (e). We seek comment on these proposals and ways to simplify the proposed policies.

2. Proposed Changes to § 414.84(b) and (c)

We propose to amend § 414.84(b) and (c) to update the amount of the performance payments for the core sessions, core maintenance sessions and ongoing maintenance sessions (where applicable) to be consistent with the proposal herein. We propose that this change apply to all MDPP beneficiaries starting the MDPP set of services on or after January 1, 2022.

For those MDPP beneficiaries who started the first core session on or before December 31, 2021, we propose that MDPP suppliers continue to submit claims for the ongoing maintenance sessions attended using the existing ongoing maintenance HCPCS G-codes, G9891, G9892, G9893, G9894, and G9895 when submitting claims for those MDPP beneficiaries who attended ongoing maintenance sessions.

We are proposing to amend our regulation at § 414.84(b) and (c). We seek comment on these proposals.

3. Proposed Changes to § 424.205(b)

Medicare requires all organizations that deliver MDPP services to enroll separately in Medicare as a MDPP supplier and pay an enrollment application fee. This places a unique burden on MDPP suppliers. Approximately 39 percent of these entities are non-traditional suppliers that serve their local communities to increase diversity, equity, and inclusion of their services, including but not limited to YMCAs, county health departments, community health centers, and non-profit organizations that focus on health education that otherwise would neither enroll nor be able to enroll as a Medicare supplier. Indeed, they are often very different from most other Medicare providers and suppliers in terms of business model and financial wherewithal, and they frequently furnish non-health care services to the community. In this vein, they cannot be considered in the same light as, for example, hospitals, skilled nursing facilities, ambulance suppliers, or other organizations specifically and exclusively designed for the provision of health care services.

The provider/supplier enrollment fee for CY 2021 is $599. Although MDPP suppliers may submit a written request to CMS for a hardship exception to the application fee in accordance with § 424.514, many would not qualify. We have heard from stakeholders that the enrollment application fee factors into an organization's decision to participate in MDPP. Organizations must submit the provider enrollment fee during the initial start-up phase of their expanded model implementation. This is when costs are likely the highest for organizations and the timing of the first CMS reimbursement is farthest away. MDPP suppliers would need to provide a first core session to at least 24 beneficiaries to simply recoup the Medicare provider enrollment fee. For many potential MDPP suppliers, the provider enrollment application fee, when combined with the additional MDPP requirements, such as the claims processing requirements, result in an organization declining to invest in enrolling as an MDPP supplier.

On April 9, 2020, CMS, through the COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers, waived all provider enrollment application fees. We saw an immediate increase in MDPP supplier enrollment in Q2 2020, the quarter the blanket waivers were announced, but MDPP supplier enrollment slowed thereafter, likely due to the impact of the pandemic and many CDC National DPP organizations pausing their delivery of DPP. We believe that granting a waiver of the fee for MDPP suppliers to extend beyond the COVID–19 Emergency Declaration Blanket Waiver may increase MDPP supplier enrollment, which will ultimately improve beneficiary access to the expanded model and our ability to evaluate the outcome of the MDPP because increasing the number of MDPP suppliers may provide for a more robust evaluation of the expanded model. Given our prior discussion of the unique character of MDPP suppliers in comparison to more traditional provider and supplier types, we believe this policy change is warranted.

In an effort to minimize the impact of this potential barrier and allow for a more robust expanded model evaluation, we are proposing to utilize CMS' waiver authority under section 1115A(d)(1) of the Act to waive the provider enrollment Medicare application fee (described in sections 1866(j)(2)(C)(i) and (ii) of the Act) for all organizations that submit an application to enroll in Medicare as an MDPP supplier on or after January 1, 2022. We are proposing to amend our regulation at § 424.205 (b) to reflect this waiver.

We seek comment on these proposals.

4. Proposed Changes to § 424.502

We propose to make a conforming amendment to § 424.502 to remove the reference to the CMS–20134 from the definition of ''institutional provider.'' The CY 2018 PFS final rule, which established the application fee for MDPP suppliers, amended the definition of ''institutional provider'' in section § 424.502 to state that MDPP suppliers that complete the CMS–20134 enrollment application are ''institutional provider[s]''. Thus, the application fee described in section § 424.514 applies to organizations enrolling in Medicare as MDPP suppliers. We are proposing to reverse this policy by amending § 424.502 to remove the reference to the CMS–20134 thereby removing MDPP suppliers from the list of institutional providers required to pay the Medicare enrollment fee under § 424.514. As proposed, § 424.514 would no longer be applicable to organizations enrolling in Medicare as an MDPP supplier.

We seek comment on this proposal.

M. Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions, under sections 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, April 1, 2014), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled ''Medicare Clinical Diagnostic Laboratory Tests Payment System'' (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

2. Payment for Laboratory Specimen Collection and Travel Allowance for COVID–19 Clinical Diagnostic Laboratory Tests

In general, section 1833(h)(3) of the Act requires the Secretary to provide for and establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), in addition to the amounts provided under the Medicare CLFS. Section 1833(h)(3)(A) of the Act provides that the Secretary must establish a nominal fee to cover the appropriate costs in collecting the sample on which a CDLT was performed and for which payment is made under Medicare Part B, except that not more than one such fee may be provided with respect to samples collected in the same encounter. The HCPCS codes for the nominal specimen fees currently listed on the CLFS (HCPCS codes 36415, P9612, and P9615) have a payment rate of $3. Section 216(a) of PAMA added section 1834A(b)(5) to the Act, which increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA). Therefore, effective April 1, 2014, the nominal fee that would otherwise apply for a sample collected from an individual in a SNF or by a laboratory on behalf of a HHA is $5 (see § 414.507(f)), and the relevant HCPCS code is G0471.

In addition, section 1833(h)(3)(B) of the Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In accordance with this provision, Medicare established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. Under current guidance, the travel allowance is intended to cover the estimated travel costs of collecting a specimen from a Medicare beneficiary and to reflect the technician's salary and travel costs. It is paid only when the nominal specimen collection is also payable and is not available if the technician is merely performing a messenger service to pick a specimen drawn by a physician or nursing home personnel. The methodology for determining the travel allowance varies depending on the round trip mileage to patients' homes. For instance, a per mile travel allowance methodology applies when the round trip to patients' homes is greater than 20 miles and a flat rate travel allowance methodology applies when the round trip to patients' homes is less than 20 miles. Medicare Part B MACs calculate the travel allowance for each claim. Stakeholders have reported that, in some cases, the MACs require them to maintain paper logs of miles traveled to receive the travel allowance.

Our general policies for payment of the nominal specimen collection fee and the fee to cover transportation and expenses for trained personnel to collect specimens from homebound patients and non-hospital inpatients are set forth in Pub. 100–04, Medicare Claims Processing Manual, chapter 16, section 60. We also implemented the increased nominal specimen collection fee under section 1834A(b)(5) of the Act in our regulations at § 414.507(f). The manual instructions regarding payment of these fees are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf.* Neither the annual cash deductible nor the 20 percent coinsurance for Medicare apply to the specimen collection fees or travel allowance for laboratory tests.

In the interim final rule with comment period titled, ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (March 2020 COVID–19 IFC), which displayed and became effective on

March 31, 2020, and appeared in the April 6, 2020 **Federal Register** (85 FR 19230), we established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients (85 FR 19256 through 19258). This policy provides independent laboratories with additional resources to provide COVID–19 testing and helps with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home specifically for the duration of the public health emergency (PHE) for the COVID–19 pandemic. To identify specimen collection for COVID–19 testing specifically, we established two new level II HCPCS codes: Code G2023 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (Coronavirus disease [COVID–19]), any specimen source);* and code G2024 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–Cov–2) (Coronavirus disease [COVID19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source*), for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the PHE for COVID–19.

We stated in the March 2020 COVID–19 IFC (85 FR 19258) that, in establishing a nominal fee for COVID–19 specimen collection, we considered the type of trained laboratory personnel required to collect the specimen and the resources COVID–19 specimen collection could require, and we recognized that the existing specimen collection fees were not intended to address additional resources needed during the PHE for the COVID–19 pandemic. Absent concrete information regarding the costs associated with independent laboratories collecting such specimens for COVID–19 tests in the context of the PHE, we looked to similar services in other settings of care as a potential benchmark. We identified the PFS as the best source for a potential payment amount since physicians and other practitioners often bill for services that involve specimen collection by trained, non-institutional staff.

We described how under the PFS, a Level 1 office visit (CPT® code 99211) typically does not require the presence of a physician or other qualified health care professional and the usual presenting problem(s) are minimal. This code is what is typically reported by physician practices when the patient only sees clinical office staff for services like acquiring a routine specimen sample. CPT® code 99211 describes an: *Office visit for E/M of an established patient that may be performed by clinical staff under supervision (may not require a physician's presence). Usually the presenting problem(s) are minimal and typically, 5 minutes are spent supervising or performing the service.*

We stated in the March 2020 COVID–19 IFC that, in the case of collecting a specimen for COVID–19 testing, we believe that in the context of and for the duration of the PHE for the COVID–19 pandemic, collecting specimens using nasopharyngeal and oropharyngeal swabs or collection of sputum will require a trained laboratory professional, as well as additional precautions that must be taken to minimize exposure risks in handling specimens that are suspected or confirmed for COVID–19. Thus, we believe that collecting a specimen for COVID–19 testing may incur higher costs than similar specimen collection services, which require a trained laboratory professional, but not additional precautions, to minimize exposure risk.

We indicated in the March 2020 COVID–19 IFC that this specimen collection fee policy was established for the duration of the PHE for COVID–19 (85 FR 19256) and will end once the PHE for the COVID–19 pandemic has ended.

In the CY 2021 PFS proposed rule, we requested comments on whether we should delete HCPCS codes G2023 and G2024 once the PHE for COVID–19 ends (85 FR 50211). Specifically, we sought public input on why these codes, and their corresponding payment amounts, which are higher than the nominal specimen collection fees for other conditions, would be necessary or useful outside of the context of the PHE for COVID–19. We stated that we were particularly interested in why separate, increased payment for specimen collection, specifically for COVID–19 tests, in contrast to other tests, may be needed following the end of the PHE. We noted that comments received may inform a future proposal.

We received public comments on the laboratory specimen collection fees for COVID–19 CDLTs. Commenters expressed support for permanently extending payment for specimen collection for COVID–19 CDLTs after the PHE ends, as commenters expect the COVID–19 virus to be present into CY 2021, thus making it appropriate for CMS to continue to pay laboratories for specimen collection using HCPCS codes G2023 and G2024. Commenters recommended that we expand and permanently authorize the specimen collection fees under HCPCS codes G2023 and G2024 to apply to all CDLTs to compensate for the supplies, equipment, and sterilization protocols required for safe and uncontaminated specimen collection and handling in the presence of COVID–19. Commenters noted that COVID–19 will continue to spread and may become an ongoing and/or seasonal infectious disease event, and because of this possibility, they expect that the heightened safety precautions, the need for personal protective equipment (PPE), and the requirement for special training for specimen collection will persist beyond the immediate PHE. In the CY 2021 PFS final rule (85 FR 84695), we noted that we planned to take this feedback into consideration for possible future rulemaking or guidance regarding the nominal specimen collection fees and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing.

After considering these comments, we continue to believe that the laboratory specimen collection fees for COVID–19 CDLTs established in the context of and for the duration of the PHE for the COVID–19 pandemic should conclude at the termination of the PHE, as originally announced in the March 2020 COVID–19 IFC (85 FR 19258). We believe that these increased payments for specimen collection specifically for COVID–19 tests would no longer be warranted beyond the end of the PHE. As described above, the increased fees were intended to address additional resources needed specifically during the PHE for the COVID–19 pandemic, particularly for the collecting of specimens using nasopharyngeal and oropharyngeal swabs or collection of sputum, which required a trained laboratory professional and additional precautions to minimize exposure risks in handling specimens that are suspected or confirmed for COVID–19. Given the advances in the types of COVID–19 CDLTs available to the public and the reduced need for specimen collection by trained laboratory professionals, we believe that the increased laboratory professional resources needed for COVID–19 specimen collection will no longer be necessary after the PHE for the COVID–19 pandemic ends. Additionally, we expect that the termination of the PHE will occur when there is a reduced risk of COVID–19, which will mean the increase of supplies, PPE, and heightened sterilization and safety

protocols for laboratory specimen collection and handling will be at a more manageable level. Likewise, we expect the potential ongoing spread of COVID–19 likely will diminish after the PHE ends, which will mean that advanced safety precautions, extensive PPE, and specialized training for laboratory specimen collection likely will no longer be required to the same extent as during the PHE. Furthermore, we anticipate that widespread vaccination of both medical professionals as well as the general population will likely reduce the need for intensive PPE.

3. Comment Solicitation on Specimen Collection Fee and Travel Allowance for Clinical Diagnostic Laboratory Tests

Although we expect the increased specimen collection fees for COVID–19 CDLTs will end at the termination of the PHE for the COVID–19 pandemic, we are taking this opportunity to seek broad comment on our policies for specimen collection fees and the travel allowance as we consider updating these policies in the future through notice and comment rulemaking. Therefore, in this proposed rule, we are requesting comments regarding the nominal specimen collection fees for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital). We are also seeking comments related to the calculation of costs for transportation and personnel expenses for trained personnel to collect specimens from such patients.

We are seeking additional public input regarding considerations for the nominal fees for laboratory specimen collection for COVID–19 testing beyond the PHE. We are particularly interested in what additional resources might be needed for specimen collection for COVID–19 CDLTs and other tests after the PHE ends. For example, laboratories may see a benefit to using more PPE for laboratory staff than they did before the onset of the PHE as way to improve safety for personnel and patients. We expect there will be ongoing interest in minimizing outbreaks of diseases such as influenza in various settings, including SNFs, where beneficiaries may not be able to travel to a laboratory for testing. We seek feedback from stakeholders regarding how their specimen collection practices may have changed as a result of, or from insight gained during, the PHE for the COVID–19 pandemic, specifically in terms of changes to supplies and staffing resources as well as related costs. We recognize that the COVID–19 pandemic may have changed the approaches to specimen collection for laboratory testing from homebound patients and inpatients (not in a hospital) in ways that will persist beyond the termination of the PHE for the COVID–19 pandemic, and we want to understand these changes to inform potential modifications to our laboratory specimen collection policies in the future.

We also seek comments on the methodology for calculating the travel allowance, including calculation of mileage specific to per mile or flat rate and proration when there are multiple patients or specimens.

Comments received may inform a future proposal.

4. Medicare Clinical Laboratory Fee Schedule: Electronic Travel Logs

In addition to insights we have gained, and are seeking to gain, from the COVID–19 CDLT laboratory specimen collection fees policies we implemented for the duration of the COVID–19 PHE, we have also had the opportunity to gain insight about other CLFS policies established for the purposes of the PHE for COVID–19.

As described in the March 2020 COVID–19 IFC (85 FR 19256), and noted above, section 1833(h)(3)(B) of the Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In accordance with this provision, Medicare established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. The travel allowance is intended to cover the estimated travel costs of collecting a specimen from a Medicare beneficiary and reflect the technician's salary and travel costs. It is paid only when the nominal specimen collection is also payable and is not available if the technician is merely performing a messenger service to obtain a specimen drawn by a physician or nursing home personnel. The methodology for determining the travel allowance varies depending on the round trip mileage to patients' homes. For instance, a per mile travel allowance methodology applies when the round trip to a patients' home is greater than 20 miles and a flat rate travel allowance methodology applies when the round trip is less than 20 miles.

We stated in the March 2020 COVID–19 IFC (85 FR 19258) that Medicare payment for transportation and expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital) for purposes of COVID–19 testing would be made in accordance with existing instructions found in the Medicare Claims Processing Manual. Our policies for payment of the fee to cover transportation and expenses for trained personnel to collect specimens from homebound patients and non-hospital inpatients are set forth in Pub. 100–04, Medicare Claims Processing Manual, chapter 16, section 60.

Medicare Part B MACs calculate the travel allowance for each claim, and we understand from stakeholders that, in some cases, the MACs have required laboratories to maintain paper logs of miles traveled to receive the travel allowance. In the March 2020 COVID–19 IFC (85 FR 19258), we noted that stakeholders reported to us that maintaining paper logs of miles is burdensome, whereas maintaining electronic logs is less burdensome, especially with the development of GPS systems and various applications for cellular phones in recent years that can track miles traveled. We indicated that, for the duration of the PHE for the COVID–19 pandemic, paper documentation of miles traveled would not be required and that laboratories could maintain electronic logs if they preferred. However, we indicated that laboratories would need to be able to produce these electronic logs in a form and manner that could be shared with MACs, and that the MACs may provide more information on acceptable formats.

We understand that laboratories have benefited from the operational guidance we announced in the March 2020 COVID–19 IFC to permit them to use electronic rather than paper logs of miles traveled. Using electronic logs reduces administrative burden for laboratories and their staffs, as we understand from stakeholders that paper logs are extremely time- and resource-intensive and they have requested that CMS provide flexibilities for the use of electronic logs. Paper logs require storage, which can be a burden to laboratories. Additionally, manipulation of paper logs is time- and labor-intensive, which could increase laboratory costs. Therefore, we are making permanent the option for laboratories to maintain electronic logs of miles traveled for the purposes of covering the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a specimen sample. To be clear, this option for laboratories to maintain electronic logs is not limited to COVID–19 specimen collection, but

rather, applies to specimen collection for any CDLT. We are announcing electronic logs as a permanent option in this proposed rule, and will provide guidance in future instructions via forthcoming Change Requests and other materials such as MLN Matters® Articles. Laboratories will need to be able to produce electronic logs in a form and manner that can be shared with MACs, and should continue to consult with their local MACs regarding the format and process for ongoing submission of this information.

N. Medicare Provider and Supplier Enrollment

1. Enrollment Process

a. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all federal and state requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Since 2006, we have taken steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS–855 (OMB Control No. 0938 0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider or supplier meets all applicable Medicare requirements.

We believe the Medicare provider enrollment screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse. As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as discussed further in this section II.N. of this proposed rule, we propose several changes to our existing provider enrollment regulations.

b. Legal Authorities

There are two principal categories of legal authorities for our proposed provider enrollment provisions. First, section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers. Second, sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

2. Proposed Provisions

a. Expansion of Authority To Deny or Revoke Based on Office of Inspector General (OIG) Exclusion

Under §§ 424.530(a)(2) and 424.535(a)(2), respectively, CMS denies or revokes a provider's or supplier's enrollment if the provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier is excluded by the OIG. We propose several changes related to these authorities.

First, we propose to expand the categories of parties within the purview of these denial and revocation provisions to include excluded administrative or management services personnel who furnish services payable by a federal health care program, such as a billing specialist, accountant, or human resources specialist. This change would align with existing OIG guidance stating that providers and suppliers may not employ excluded persons to provide management or administrative services that are payable by a federal health care program.[119] Such individuals can impact a provider's or supplier's operations in a manner harmful to the interests of the Medicare program; for example, an individual in a lower-level administrative position could undertake fraudulent activity to the same extent (and with consequences as severe) as a high-ranking officer. For program integrity purposes, the central issue is not the specific individual who engaged in the abusive conduct, but the conduct itself. Accordingly, we believe this regulatory revision is necessary to protect Medicare and its beneficiaries.

Second, existing § 424.530(a)(2) references ''other health care personnel furnishing Medicare reimbursable services who is required to be reported on the enrollment application.'' (Section 424.535(a)(2) does not contain the entirety of this clause.) To conform to our change described in the previous paragraph, we propose to replace this language with ''other health care or administrative or management services personnel furnishing services payable by a federal health care program.'' This would ensure consistency with the previously referenced OIG guidance, which, we note, is not restricted to services: (1) Only reimbursable by Medicare; or (2) furnished by individuals listed on a Medicare enrollment application. We would also include this language within § 424.535(a)(2) so that the latter aligns with § 424.530(a)(2).

Third, § 424.535(e) states that if the revocation was due to adverse activity (sanction, exclusion, or felony) against an owner, managing employee, authorized or delegated official, medical director, supervising physician, or other personnel of the provider or supplier furnishing Medicare reimbursable services, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification. For the reasons already outlined, we propose to replace the language in § 424.535(e) concerning other personnel furnishing Medicare reimbursable services with ''other health care or administrative or management services personnel furnishing services payable by a federal health care program.''

[119] *https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.*

b. Deny or Revoke Enrollment for Surrender of Drug Enforcement Administration (DEA) Certificate of Registration in Response To Show Cause Order

We have existing authority under § 424.530(a)(11)(i) to deny a physician's or other eligible professional's enrollment if his or her DEA certificate of registration to dispense a controlled substance is currently suspended or revoked; a concomitant authority to revoke enrollment in this circumstance is outlined in § 424.535(a)(13)(i). We propose to expand these authorities to include situations where the physician or other eligible professional surrenders his or her DEA certificate in response to an order to show cause.

We have encountered situations where a physician or other eligible professional who has engaged in improper prescribing or other DEA-monitored activities relinquishes his or her DEA certificate pending a DEA show cause order so as to avoid a likely suspension or revocation of his or her DEA certificate or other similar circumstance. We believe these scenarios are no less serious from the standpoints of program integrity and beneficiary safety than a DEA certificate suspension or revocation. Hence, we believe this proposed change is warranted.

c. Creation of Specific Rebuttal Rights for Deactivations

As outlined in § 424.540, deactivation means that the provider's or supplier's billing privileges are stopped (but not revoked or terminated). Deactivation is intended to protect the provider or supplier from the misuse of its billing number and to safeguard the Trust Funds from unnecessary overpayments. Under existing regulations, a provider's or supplier's billing privileges may be deactivated if the provider or supplier: (1) Does not submit any Medicare claims for 12 consecutive calendar months; (2) fails to report certain changes in its enrollment information within required timeframes; or (3) fails to fully and accurately comply with a CMS revalidation request within 90 days.[120] To reactivate one's billing privileges, current regulations state that the deactivated provider or supplier must recertify that their enrollment information on file with Medicare is correct and must furnish any missing information as appropriate (or submit a complete Form CMS–855 application if required by CMS).

Since a deactivated provider's or supplier's billing privileges are stopped, § 424.545(b) permits the affected provider or supplier to file a rebuttal in accordance with 42 CFR 405.374 (which allows rebuttals for Medicare payment suspensions). While we have outlined deactivation rebuttal procedures in subregulatory guidance, these procedures are not reflected in regulation. Consequently, we propose to revise 42 CFR part 424, subpart P to describe the deactivation rebuttal process in detail, a process that would generally mirror our existing subregulatory procedures on the topic. This would streamline and clarify the deactivation rebuttal process, promote transparency, and enable the provider community to submit feedback on our proposal.

The specific changes we propose are as follows:

- At § 424.545(b), we propose to change the language that reads ''in accordance with § 405.374 of this chapter'' to ''in accordance with § 424.546.'' Instead of continuing to reference § 405.374, we are proposing to create a new § 424.546 to address the deactivation rebuttal process. This would enable us to tailor our procedures to the unique facts and circumstances of deactivation rebuttals, which are different from payment suspensions.
- At new § 424.546(a)(1), we propose that if a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS. We believe that a 15-day period strikes an ideal balance between the need to expeditiously take measures to safeguard program integrity and the importance of ensuring that the provider or supplier has a reasonable time-period in which to submit a rebuttal.
- At new § 424.546(a)(2), we propose that CMS may, at its discretion, extend the 15-day time-period referenced in § 424.546(a)(1). This would permit CMS to account for special situations, such as the following: (1) A particularly and unusually complex deactivation case that perhaps warrants giving the provider or supplier more time to prepare its rebuttal; or (2) circumstances beyond the provider's or supplier's control prevents or would likely prevent the timely submission of its rebuttal.
- At new § 424.546(b)(1) through (4), we propose that any rebuttal must: (1) Be in writing; (2) specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or effective date, as well as the reasons for disagreement; (3) submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation; and (4) be submitted in the form of a letter that is signed and dated by the individual supplier (if the latter is enrolled as an individual physician or NPP), the authorized official or delegated official (as those terms are defined in § 424.502), or a legal representative (as defined in 42 CFR 498.10). Concerning proposed paragraph (b)(4), if the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement would be sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

We believe that the requirements of proposed § 424.546(b)(1) through (4) are necessary to ensure: (1) A uniform and standard process for submitting deactivation rebuttals; (2) that there is written documentation of the provider's or supplier's contentions; (3) that CMS has sufficient information to perform its review; and (4) that the provider or supplier authorized the rebuttal submission.

- At new § 424.546(c), we propose that the provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (a) and fully compliant with all of the requirements of paragraph (b) constitutes a waiver of all rebuttal rights under this section and § 424.545(b). This provision would not only specify the consequences of an untimely or non-compliant rebuttal but also help encourage the provider or supplier to abide by paragraphs (a) and (b) should it choose to rebut a deactivation.
- At new § 424.546(d), we propose that upon receipt of a timely and compliant deactivation rebuttal, CMS

[120] We are proposing additional grounds for deactivation in the CMS proposed rule titled, ''Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-term Care Hospital Quality Reporting Program Requirements'' (CMS–1747–P).

reviews the latter to determine whether the imposition of the deactivation and/or the designated effective date are correct. We believe this provision would adequately notify the public of the scope of CMS' review.

- At new § 424.546(e), we propose that nothing in § 424.546 or in § 424.545(b) would require CMS to delay the imposition of a deactivation pending the completion of the CMS review described in paragraph (d). That is, the filing of a rebuttal and the review period associated therewith does not suspend or postpone the deactivation's implementation. This provision, which mirrors our existing subregulatory policy on the matter, is needed so that CMS can expeditiously enforce the program integrity protections that a deactivation affords, all the while recognizing the provider's or supplier's ability to challenge the deactivation via the rebuttal process. If CMS determines under paragraph (d) that the deactivation was erroneous, it would be reversed.
- At new § 424.546(f), and consistent with both current subregulatory policy concerning deactivation rebuttals as well as payment suspension rebuttal regulations at § 405.375(c), a determination made under § 424.546 would not be an initial determination under § 498.3(b) and, therefore, would not be appealable. This would clarify for providers and suppliers that a rebuttal is the only administrative remedy available for a deactivation.

d. Modernizing Enrollment Policies for Emerging Technologies in Independent Diagnostic Testing Facilities

Section 410.33(a) states that CMS pays for diagnostic procedures under the PFS only when performed by the suppliers listed in that section. Among these supplier types are independent diagnostic testing facilities (IDTFs). An IDTF may be a fixed location, a mobile entity, or an individual NPP. It is independent of a physician's office or hospital, although the IDTF regulations outlined in § 410.33(a) also apply when an IDTF furnishes diagnostic procedures in a physician's office.

Section 410.33 as a whole contains provisions with which IDTFs must comply in order to enroll in (and maintain enrollment in) Medicare. This includes requirements for supervising physicians (§ 410.33(b)), nonphysician personnel (§ 410.33(c)), and the ordering of tests (§ 410.33(d)). In addition, § 410.33(g) contains various certification standards that IDTFs must meet. We established these standards to help ensure the quality and safety of IDTF diagnostic testing and to strengthen our ability to verify the IDTF's compliance with enrollment requirements.

IDTFs generally perform diagnostic tests on beneficiaries in, for instance, a health care facility, physician's office, or mobile setting. Indeed, the IDTF standards at § 410.33(g) (as well as other provisions at § 410.33) were designed for traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing. Yet, some health care entities have developed or utilize diagnostic tests that do not require this form of interaction. That is, certain IDTFs perform diagnostic services via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction; the service is often conducted by a technician who undertakes a computer analysis offsite or at another location at which the patient is not present. The physician then reviews the image to determine the appropriate course of action. In short, these entities generally (though not exclusively) have two overriding characteristics. First, the tests they perform do not involve direct patient interaction, meaning that the test is conducted away from the patient's physical presence and is non-invasive. Second, the test involves off-site computer modeling and analytics.

Despite the comparatively new and innovative forms of testing these entities undertake, they can still qualify as IDTFs (notwithstanding the offsite and indirect nature of the test) so long as they meet the applicable requirements of § 410.33. The dilemma is that these entities often cannot meet certain IDTF requirements (and thus cannot enroll in Medicare) strictly because of the test's indirect nature. In other words, the types of tests at issue do not fall within the category of those to which several of our standards in § 410.33 were intended to apply (specifically, to in-person procedures). To account for such technological advances in diagnostic testing, we believe that revisions to § 410.33 are necessary. To this end, we propose that IDTFs that have no beneficiary interaction, treatment, or testing at their practice location would be either partially or wholly exempt from the following requirements in § 410.33 (hereafter occasionally referenced as ''exempted'' IDTFs).

Section 410.33(c) requires all nonphysician personnel that the IDTF uses to perform diagnostic tests to demonstrate the basic qualifications to perform these tests as evidenced by state licensure or state certification. In the absence of a state licensing board, the technician must be certified by an appropriate national credentialing body. (The IDTF must also maintain documentation available for review that these requirements have been met.) However, the indirect tests in question often do not require state licensure or state/national credentialing, meaning that § 410.33(c) becomes a difficult requirement for such IDTFs to meet. Indeed, § 410.33(c) has typically been applied to the qualifications needed to perform in-person tests in traditional IDTF settings; that is, the staff at exempted IDTFs often will instead be primarily trained in the test's particular software and computer analytics (or other non-beneficiary based services)). Extending § 410.33(c)'s purview to indirect tests would reduce the number of personnel who can perform them, thus hindering beneficiary access to such services and potentially preventing the enrollment of otherwise qualified IDTFs.

Accordingly, we propose to divide current § 410.33(c) into two paragraphs. New paragraph (c)(1) would contain the existing requirements of § 410.33(c) except as stated in new paragraph (c)(2). We propose in the latter paragraph that, for services that do not require direct or in-person beneficiary interaction, treatment, or testing, any nonphysician personnel performing the test must meet all applicable state licensure requirements for doing so; if there are such state licensure requirements, the IDTF must maintain documentation available for review that these requirements have been met.

While we believe that personnel performing the tests described in proposed paragraph (c)(2) should meet whatever state requirements exist for those services, paragraph (c)(2) would not include any reference to national credentialing bodies. Further, we recognize that, in some instances, states may have no requirements for technicians involved in the particular type of computer analytics involved in the Medicare-covered service.

We also propose that the following IDTF certification standards in § 410.33(g) would not apply to the aforementioned exempted IDTFs:

- The IDTF must have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF (§ 410.33(g)(6)).
- The IDTF must answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (§ 410.33(g)(8)). (For mobile IDTFs, this documentation would be stored at their home office.)

• The IDTF must openly post the standards outlined in § 410.33(g) for review by patients and the public (§ 410.33(g)(9)).

Concerning § 410.33(g)(8), we note that exempted IDTFs would not be furnishing direct services to beneficiaries that could result in a beneficiary's written clinical complaint. Thus, we believe this standard should be inapplicable to exempted IDTFs, and we would revise paragraph (g)(8) in this vein. We propose a similar approach with § 410.33(g)(9); neither beneficiaries whose tests are sent to the exempted IDTF nor the public in general will visit its physical location, therefore negating the need for a posting of standards.

As previously mentioned, we also propose that § 410.33(g)(6) would not apply to exempted IDTFs. The liability policy addressed therein was designed for IDTFs that provide services to beneficiaries in a facility or mobile unit and thus could have issues concerning medical negligence and/or malpractice. Nevertheless, we recognize that a chain of liability could involve an exempted IDTF if a computer malfunction or other error arose in the IDTF's diagnostic services. To illustrate, a software problem could lead to inaccurate test results, which in turn might result in an incorrect interpretation by a beneficiary's physician and ultimately harm the beneficiary. There could be other instances, too, where the performance of a particular test raises questions of possible liability. Consequently, we are soliciting public comment on the types of situations where this could arise as well as on the following issues: (1) Whether exempted IDTFs should indeed be required to maintain a $300,000 liability policy; (2) if § 410.33(g)(6) remains an exception, whether a liability amount of less than $300,000 is warranted and, if so, what that amount should be (for example, $50,000 or $100,000 or $200,000); and (3) whether no liability policy should be required.

In short, we believe that applying the foregoing exemptions to IDTFs that have developed innovative proprietary software for diagnostic testing where no patient interaction is involved would benefit the Medicare program and its beneficiaries by encouraging new IDTF technologies and services. We welcome comments on our proposed exemptions, and we specifically request comment on whether to retain and modify the IDTF standards in § 410.33(g)(6), (8), and (9) for the aforementioned exempted IDTFs, rather than waive those requirements for them.

e. Proposed Revisions at § 424.535(a)(8)

Under § 424.535(a)(8)(ii), CMS may revoke a provider's or supplier's enrollment if CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. The purpose of this provision is to place providers and suppliers on notice that they are legally obligated to always submit correct and accurate claims and that failing to do so could lead to the revocation of their enrollment; indeed, the submission of non-compliant claims places the Trust Funds at risk due to the potential for erroneous payments. In determining whether a revocation is appropriate under § 424.535(a)(8)(ii), CMS considers, as appropriate and applicable, the factors outlined in § 424.535(a)(8)(ii)(A) through (F); respectively, these are:

(A) The percentage of submitted claims that were denied.

(B) The reason(s) for the claim denials.

(C) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

(D) The length of time over which the pattern has continued.

(E) How long the provider or supplier has been enrolled in Medicare.

(F) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

We have recently encountered situations where providers and suppliers have engaged in periods of non-compliant billing that, though comparatively brief, have or could have harmed the Medicare program. While we have attempted revocation action per § 424.535(a)(8)(ii) against such providers and suppliers, the current wording of some of the factors in paragraphs (a)(8)(ii)(A) through (F) have hampered our ability to do so. To increase our flexibility to address periods of abusive billing irrespective of their duration, we believe we must revise § 424.535(a)(8)(ii)(A) through (F) as follows:

• In paragraph (a)(8)(ii)(A), we propose revisions to focus on the percentage of denials within subsets of the provider's or supplier's claim submissions rather than across the entire universe of their claim submissions. Specifically, we would consider the percentage of submitted claims that were denied during the timeframe under consideration. We believe existing paragraph (a)(8)(ii)(A) inhibits our capacity to target brief periods involving a significant percentage of denied claims; this is because this factor has been interpreted to require said percentage to be weighed against claim denials over the entire period of the provider's or supplier's enrollment. As proposed, revised paragraph (a)(8)(ii)(A) would better enable CMS to address these non-compliant periods by restricting the scope of denial percentages to a shorter timeframe. For example, assume Provider X enrolled in Medicare on February 1. Although only a small percentage of its claims were denied through June 30, the denial rate was very high between July 1 and July 31. Under our proposed change, our period of review could be limited to July. This reflects our view that even a comparatively short timeframe of improper billing can threaten the Trust Funds, as evidenced by the aforementioned cases we have seen. We reiterate that the submission of non-compliant claims generates a risk of improper payments, which could lead to thousands or even millions of Medicare dollars being paid pursuant to either a lengthy or brief billing period.

• For reasons similar to our proposed revision of § 424.535(a)(8)(ii)(A), we propose to remove § 424.535(a)(8)(ii)(D) altogether. As already indicated, short but very intense periods of improper billing can endanger the Medicare program no less than a longer pattern of non-compliant yet merely moderate-volume billing. Yet the ''length of time'' standard in paragraph (a)(8)(ii)(D) often deters us from taking action under paragraph (a)(8)(ii) to address these shorter timeframes. Given this, we believe that eliminating paragraph (a)(8)(ii)(D) would strengthen our program integrity efforts.

• We also propose to remove § 424.535(a)(8)(ii)(E), which addresses the length of the provider's or supplier's enrollment. We consider this factor to be largely immaterial to the issue of whether a pattern of improper billing exists. More importantly, it can hinder our ability to utilize § 424.535(a)(8)(ii) as a whole. We have encountered fraud schemes where providers and suppliers enroll in Medicare, bill inappropriately, and then leave the program after a brief timeframe. We believe the enrollment length in these and other cases of non-compliant billing should have no bearing on whether paragraph (a)(8)(ii) can be applied, for the main issue is the behavior itself and not the period of enrollment.

• We propose to remove § 424.535(a)(8)(ii)(B) as well. Notwithstanding our original inclusion of this factor in paragraph (a)(8)(ii), the overall purpose of paragraph (a)(8)(ii) has always been to deter non-compliant

billing, regardless of the reason for it. Even if a period of erroneous claim submissions reflected no nefarious intent by the provider, the latter still failed to comply with Medicare billing requirements and this presented a risk to the Medicare program. For this reason, we do not view the claim denial reason as particularly germane to the question of whether paragraph (a)(8)(ii) should apply in a particular case.

- In addition, we propose to add new paragraph (a)(8)(ii)(C) by which we would consider the type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined). We believe this paragraph would provide greater specificity than the broader, catch-all factor at § 424.535(a)(8)(ii)(F) (which we would nonetheless retain). It would also allow us to more narrowly tailor our review to the unique facts of the case, thus also strengthening our ability to consider any aggravating or mitigating circumstances.

Given the foregoing, paragraph (a)(8)(ii) would include the following factors, respectively designated as paragraphs (A) through (D):

- The percentage of submitted claims that were denied during the period under consideration.
- Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.
- The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).
- Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

We recognize that these revisions would represent a reduction in the number of factors we would consider. However, we believe the remaining criteria would still give the provider or supplier fair consideration in our determinations while permitting us to address a wider range of non-compliant billing periods in order to protect the Medicare program.

2. Provider/Supplier Medical Review Requirements

a. Background

CMS identifies improper payments in the Medicare Fee-for-Service (FFS) program through a variety of program integrity-related activities, and we use a network of contractors to carry out program integrity initiatives, including Recovery Audit contractors (RACs), the Supplemental Medical Review Contractor (SMRC), Unified Program Integrity Contractors (UPICs), Medicare Administrative Contractors (MACs), and the Comprehensive Error Rate Testing (CERT) contractor. (We are purposely excluding Quality Improvement Organizations (QIOs) from this discussion and the following proposals since QIOs are governed by separate and distinct statutory and regulatory requirements. For information about the QIOs, see sections 1151–1163 of the Act and 42 CFR parts 475–480.)

Both UPICs and MACs perform prepayment medical review, while the RACs, SMRC, UPICs, MACs, and CERT all perform post-payment medical reviews. Both prepayment medical reviews and post-payment medical reviews are used by our contractors to determine, among other things, whether items or services are reasonable and necessary under section 1862(a)(1) of the Act. In carrying out these reviews, each contractor requests additional documentation from providers and suppliers, which the contractors then assess to either support the payment of claims or conversely, deny (in full or in part) claims thereby protecting the Medicare Trust Funds against improper payments. Our contractors may also carry out follow-up prepayment or post-payment reviews on the same providers or suppliers to ensure improper payments are not continuing.

Our contractors are authorized to request additional documentation through multiple statutory authorities, including sections 1815(a), 1833(e) and 1862(a)(1)(A) of the Act. Sections 1815(a) and 1833(e) of the Act provide that no payments shall be made to any provider or supplier unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider for the period with respect to which the amounts are being paid or any prior period. Under section 1862(a)(1)(A) of the Act, payment must generally be limited to those items and services that are reasonable and necessary.

b. Proposal for Regulations Governing Prepayment and Post-Payment Medical Review

Despite the statutory authority authorizing our contractors' activities, we do not have regulatory provisions governing certain medical review activities, specifically prepayment and post-payment medical reviews. In this proposed rule, we are proposing key terms and definitions associated with these two review types; language codifying a contractors' authority to request additional documentation within established timeframes; and provisions detailing a provider's or supplier's responsibility to comply with requests for additional documentation, including the impact should a provider or supplier fail to comply with a request. These provisions are based on existing operational practices used by our contractors. We believe that adding these provisions in regulation will enhance provider and supplier understanding of our review processes, as well as, improve consistency among our contractors.

c. Proposed Key Terms and Definitions

To ensure consistency across prepayment and post-payment reviews and establish clear requirements, we propose adding the following key terms and their definitions to § 405.902: ''Additional documentation'' means the information requested by a contractor when conducting a prepayment review or post-payment review; ''Additional Documentation Request (ADR)'' means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review; ''Post-payment medical review (or post-payment review)'' means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate; and ''Prepayment medical review (or prepayment review)'' means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made. These definitions would be consistent with longstanding manual language and common use of these terms by our contractors.

d. Prepayment and Post-Payment Medical Review

We are proposing to add new § 405.903 to outline the prepayment medical review provisions.

- At paragraph (a), we are proposing to codify our contractors' authority to conduct prepayment medical review on selected claims in order to determine whether and how much payment should be made.
- At paragraph (b), we are proposing language detailing our contractors' authority to request additional documentation while conducting a prepayment review.
- At paragraph (b)(1), we are proposing that a provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request except as stated in paragraphs (b)(2) and (c).
- At paragraph (b)(2), we are proposing that a contractor may accept documentation received after 45

calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

• At paragraph (c), we are proposing language detailing a UPIC's authority to provide 30 calendar days to a provider or supplier submitting additional documentation and that a UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

These provisions reflect longstanding requirements MACs and UPICs have used in conducting prepayment reviews. The different time-periods within which additional documentation must be received is based on unique processing requirements for each contractor. Although both conduct prepayment reviews, the UPICs work directly with law enforcement and focus on potentially fraudulent providers or suppliers. Thus, the different timeframes for receiving additional documentation is necessary to account for the distinction and enables each type of contractor to appropriately balance their need for documentation in completing reviews with the potential burden on providers and suppliers should reviews take longer than is warranted. Efforts to limit the burden placed on providers and suppliers as much as possible is also warranted so that patient care is not unnecessarily impacted.

Additionally, both MACs and UPICs historically have had the authority to accept documentation received after the initial timeframe has expired based on good cause, such as natural disasters, interruptions in business practices, or other extenuating circumstances. These circumstances are best determined on a case-by-case basis by the MAC or UPIC, and the proposed language at paragraphs (b)(2) and (c), respectively, convey the MAC and UPIC authority to determine that good cause exists to warrant accepting documentation received after the initial timeframe given.

• At paragraph (d), we propose to specify that a contractor's prepayment review will result in an initial determination under § 405.920. Again, this has been the longstanding approach to the results of prepayment reviews.

We are also proposing similar provisions at new § 405.929 regarding post-payment medical reviews.

• At paragraph (a), we are proposing language outlining our contractors' authority to select claims and conduct post-payment medical reviews.

• At paragraph (b), we are proposing language that specifies our contractors' authority to request additional documentation.

• At paragraph (b)(1), we are proposing that a contractor will give a provider or supplier 45 calendar days to submit additional documentation in response to a request except as stated in paragraphs (b)(2) and (c).

• At paragraphs (b)(2) and (c), we propose that a contractor may accept documentation received after 30 days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

• At paragraph (c), we are proposing language that specifies the UPIC's authority to provide 30 calendar days when requesting additional documentation and that a UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

• At paragraph (d), we propose that when conducting a post-payment review, a contractor's review will result in either no change or a revised determination under § 405.984.

As with prepayment reviews, these provisions reflect longstanding requirements UPICs and MACs, RACs, the CERT contractor, and SMRC have used in conducting post-payment reviews. While the MACs, RACs, CERT contractor, and SMRC have relatively comparable medical review processes, the UPICs are somewhat different given their close working relationship with law enforcement and focus on potentially fraudulent providers or suppliers. Thus, the different timeframes for receiving additional documentation is necessary to account for the distinction and enables each contractor to appropriately balance their need for documentation in completing reviews with the potential burden on providers and suppliers should reviews take longer than may be expected. Efforts to limit the burden placed on providers and suppliers as much as possible is also warranted so that patient care is not unnecessarily impacted.

Given that for post-payment reviews the claims have already been paid, all the contractors have historically had the authority to accept documentation received after the initial timeframe has expired based on good cause. As with prepayment reviews, this may include situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the specific contractor deems good cause in accepting the document after 30 or 45 calendar days. These circumstances are best determined on a case-by-case basis, and the proposed language at paragraphs (b)(2) and (c) convey the authority to determine that good cause exists to warrant accepting documentation received after 30 or 45 calendar days.

We are also proposing to add new § 405.930 to clearly outline our contractors' authority to deny a claim should a provider or supplier fail to convey the additional documentation in response to a request. The proposed language clarifies that the contractor must give the provider or supplier notice and time to respond to the additional documentation request. Contractors have authority to require additional documentation through multiple statutory provisions, including sections 1815(a), 1833(e) and 1862(a)(1)(A) of the Act. While our contractors maintain discretion to provide additional time to a provider or supplier in responding to an additional documentation request, our contractors also have the authority to deny additional time and the associated claim(s) when the additional documentation is not received within the requested timeframe.

We are also proposing to revise the section heading of § 405.986(a) to read, ''Establishing good cause for reopening.'' This revision clarifies the distinction made between the process for establishing good cause to reopen an initial determination made on a claim, and the good cause factors that may be applied in accepting documentation submitted after the applicable timeframes in §§ 405.903 and 405.929. In establishing criteria to determine whether to accept late documentation in response to an ADR, we are adopting the criteria set forth in §§ 405.903 and 405.929, and we are not utilizing the good cause criteria for reopening an initial determination on a claim in § 405.986. We believe this change will add further clarification to the substantive text to reflect that the section only applies to reopenings of initial determinations on a claim.

O. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. In the CY 2021 PFS final rule (85 FR 84683 through 84688), we adopted new add-on codes for take home supplies of nasal naloxone and injectable naloxone. We are continuing to monitor Medicare enrollment by OTPs and utilization of the new benefit to ensure that Medicare beneficiaries have appropriate access to care as well as monitoring for fraud, waste, and abuse. For CY 2022, we are proposing several refinements to the regulations governing Medicare coverage and payment for OUD treatment services furnished by OTPs.

2. Annual Updates

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy under which the payment for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. The payment for the non-drug component of the bundled payment for OUD treatment services will be updated annually based upon the Medicare Economic Index (MEI) (84 FR 62668 and 62669). The current payment rates, as finalized in the CY 2021 PFS final rule, both with and without locality adjustments, can be found on the CMS OTP website under Billing and Payment at *https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf*. The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2022, will be made available at the time of publication of the CY 2022 PFS final rule.

3. Proposed Refinements to Regulations Governing Medicare Payment to OTPs

In the CY 2021 PFS final rule (85 FR 84684 through 84685), we extended the definition of OUD treatment services to include short acting opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, such as naloxone, and overdose education furnished in conjunction with opioid antagonist medication. We also established an adjustment to the weekly bundled payments when the OTP furnishes take-home supplies of these medications at § 410.67(d)(4)(i)(E). This adjustment includes both a drug component and a non-drug component for overdose education. The payment for the drug component of the adjustment will be determined using the methodology in § 410.67(d)(2)(i), and will be updated annually using the most recent data available at the time of ratesetting. The amount of the non-drug component of the adjustment, which includes overdose education, will be determined based on the CY 2020 Medicare payment rate for CPT code 96161; however, we did not explicitly address either geographic adjustments or annual updates to this payment rate.

In the CY 2020 PFS final rule (84 FR 62666 through 62667), we finalized the application of a geographic adjustment to the non-drug component of the OTP bundled payments, as well as the add-on payment adjustments for non-drug services, using the Geographic Adjustment Factor (GAF). We explained that unlike the national pricing of drugs, the costs for the services included in the non-drug component of the OTP bundled payment for OUD treatment services are not constant across all geographic localities. For example, OTPs' costs for rent or employee wages could vary significantly across different localities and could potentially result in disparate costs for the services included in the non-drug component of OUD treatment services, therefore, we stated we believed it would be appropriate to apply a geographic locality adjustment to the non-drug component of the bundled payments. We also specifically stated our belief that the same logic regarding the differential costs for those services included in the bundled payments would apply and should be recognized for add-on payment adjustments for non-drug services. This geographic adjustment is codified in the regulations at § 410.67(d)(4)(ii).

Additionally, in the CY 2020 PFS final rule we finalized an annual update to the non-drug component of the bundled payment for an episode of care based upon the MEI (84 FR 62668 through 62669). We noted that we believed the same logic regarding the potential for changes in the costs of the services included in the non-drug component of the bundled payment rates also applied to the add-on payment adjustments for non-drug services. This annual update is codified in the regulations at § 410.67(d)(4)(iii).

As noted previously, when we adopted the adjustment to the weekly bundled payments for take-home supplies of opioid antagonist medications in the CY 2021 PFS final rule, we did not specifically address either geographic adjustments or annual updates to the non-drug component of this adjustment and did not update the provisions governing the geographic adjustment and annual update in order to reference the new adjustment. Because the adjustment for take-home supplies of opioid antagonist medications includes a non-drug component, we believe the same considerations regarding varying costs based on geographic locality and the need for annual updates apply. Accordingly, we are proposing to revise the regulation at § 410.67(d)(4)(ii) to include the adjustment for take-home supplies of opioid antagonist medications in the list of items for which the non-drug component will be geographically adjusted using the GAF. We are also proposing to revise the regulation at § 410.67(d)(4)(iii) to include the adjustment for take-home supplies of opioid antagonist medications in the list of items that will be updated annually using the MEI.

Additionally, in the CY 2021 PFS final rule (85 FR 84688), we explained that consistent with § 410.67(d)(5), any payment to an OTP for naloxone would be duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service, and that we would recoup any duplicative payment made to an OTP for naloxone. However, the regulation on duplicative payments at § 410.67(d)(5) does not specifically reference payments for medications that are furnished as part of an adjustment to the bundled payment. Accordingly, we are also proposing to revise § 410.67(d)(5) to state explicitly that payments for medications that are delivered, administered or dispensed to

a beneficiary as part of an adjustment to the bundled payment are considered a duplicative payment if a claim for delivery, administration or dispensing of the same medication(s) for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. Consistent with the policies finalized in the CY 2020 PFS final rule (84 FR 62663 through 62664) regarding duplicative payments for medications dispensed as part of the weekly bundle, we believe that it is appropriate to also ensure that Medicare payments for drugs provided as an add-on to the bundled payment rate are not duplicative. We note that this proposed revision would apply not only to duplicative payments for take-home supplies of naloxone, but also to duplicative payments for additional take-home supplies of other medications that are made under § 410.67(d)(4)(i)(D).

We seek comment on these proposed changes.

4. Proposed OTP Coding and Payment for New Nasal Naloxone Product

We are aware that the FDA recently announced the approval of a new, higher dose naloxone hydrochloride nasal spray product used to treat opioid overdose and that the newly approved product delivers 8mg of naloxone.[121] In the CY 2021 PFS final rule (85 FR 84683 through 84685), we finalized payment for HCPCS code G2215 (*Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program*); *List separately in addition to code for primary procedure*). HCPCS code G2215 was priced based on an assumption of a typical case in which the beneficiary would be provided with a box of two 4mg nasal spray products. At the time of drafting this proposed rule, we do not yet have any available pricing information for this newly approved product. However, in order to be able to make payment to OTPs under Medicare for this product, we are proposing to create a new G-code describing a take-home supply of this higher dose naloxone hydrochloride nasal spray product.

Under this proposal, we would price this new add-on code based on the established methodology under the OTP benefit for determining the adjustment for take-home supplies of opioid antagonist medications at § 410.67(d)(4)(i)(E). This adjustment includes both a drug component and a non-drug component. The amount of the drug component of the adjustment would be determined using the methodology for pricing the drug component of an episode of care at § 410.67(d)(2)(i). Accordingly, consistent with the approach used to price the drug component of HCPCS code G2215, we would apply the payment methodology set forth in section 1847A of the Act to determine the payment for the new naloxone hydrochloride nasal spray product, except that payment amounts that are determined based on ASP or wholesale acquisition cost (WAC) would not include any add-on percentages (85 FR 84685). As stated in the CY 2021 PFS final rule (85 FR 84685), we believe using ASP provides a transparent and public benchmark for manufacturers' actual pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices. Additionally, we would price the drug component of the code based on an assumption of a typical dosage for a take-home supply of this new product to be a box of two 8mg nasal sprays. Consistent with the methodology established in § 410.67(d)(4)(i)(E), the amount of the non-drug component of the code would be determined based on the CY 2020 Medicare payment rate for CPT code 96161. In addition, payment for the add-on code would be limited to once every 30 days except when a further take home supply of the medication is medically reasonable and necessary. We welcome comment on this proposal.

4. Counseling and Therapy Furnished via Audio-Only Telephone

In the CY 2020 PFS final rule (84 FR 62645 and 62646), we finalized allowing the use of two-way interactive audio/video communication technology, as clinically appropriate, to furnish the counseling and therapy portions of the weekly bundle of services and additional counseling or therapy services furnished by OTPs. Due to the Public Health Emergency (PHE) for COVID–19, in the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), we revised § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, and any additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio/video communication technology for the duration of the PHE for COVID–19. Under the policy adopted in the March 31, 2020 COVID–19 IFC, counseling and therapy could be furnished using audio-only telephone calls only where two-way audio/video communications technology is not available to the beneficiary, and provided all other applicable requirements were met. In the March 31, 2020 COVID–19 IFC, we stated that we believed this change was necessary to ensure that beneficiaries with opioid use disorders would be able to continue to receive these important services during the PHE during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio/video communication technology may not be available to all beneficiaries.

We have continued to evaluate whether this flexibility would be needed after the end of the PHE. According to MedPAC's March 2021 Report to the Congress, allowing audio-only interaction for certain telehealth services can improve beneficiary choice and equity in access to care for beneficiaries who do not have access to the technology for a video telehealth visit.[122] Additionally, public comments received in response to the CY 2021 PFS proposed rule (85 FR 84691) encouraged us to reconsider our position on coverage of audio-only services following the conclusion of PHE for COVID–19 and commenters suggested that CMS consider permanently allowing OTPs to furnish certain OUD treatment services using audio-only telephone calls. Commenters stated that allowing OTPs to furnish services via audio-only interactions facilitates broader access to services, particularly for vulnerable populations, and ensures providers have flexibility to deliver care to beneficiaries as efficiently and seamlessly as possible. Given the sensitivity of OUD treatment services, commenters noted that this is an area in which more flexibility will promote not only access but also effective and sustained treatment for beneficiaries in need of care. Other commenters stated that the use of communication technology has reduced stress and stigma for those who require OUD treatment services and the allowance of

[121] *https://www.fda.gov/news-events/press-announcements/fda-approves-higher-dosage-naloxone-nasal-spray-treat-opioid-overdose.*

[122] *http://medpac.gov/docs/default-source/reports/mar21_medpac_report_ch14_sec.pdf?sfvrsn=0.*

audio-only services has greatly expanded access for beneficiaries who may not be able to use interactive video. Another commenter stated that allowing use of audio-only communication to continue after the PHE for COVID–19 would be essential in addressing disparities in healthcare, especially for dually eligible beneficiaries who do not have access to audio-visual communication technology.

After further consideration, we are persuaded by the public comments and other stakeholder feedback that using audio-only telephone calls to furnish therapy and counseling in cases where two-way audio/video communication technology is not available to the beneficiary after the end of the PHE for the COVID–19 pandemic would facilitate broader access to services. Therefore, we are proposing to allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as any additional counseling or therapy that is billed using the add-on code, using audio-only telephone calls rather than via two-way interactive audio/video communication technology following the end of the PHE for COVID–19 in cases where audio/video communication technology is not available to the beneficiary, provided all other applicable requirements are met. Accordingly, we are proposing to revise the regulations at § 410.67(b)(3) and (4) to allow OTPs to furnish therapy and counseling using audio-only telephone calls rather than via two-way interactive audio/video communication technology after the conclusion of the PHE for COVID–19 in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met. We note that we interpret the requirement that audio/video technology is ''not available to the beneficiary'' to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary.

Additionally, we are proposing that after the conclusion of the PHE for COVID–19, when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the add-on code, OTPs would be required to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to the claim. We are not proposing to require the use of this modifier when counseling and therapy services included in the weekly bundle are furnished using two-way interactive audio/video communication technology. We recognize that it may be difficult to determine which modifier to use in cases where multiple services within the bundle are furnished using different modalities, therefore, we are limiting our proposal regarding the use of modifier 95 to claim lines for the counseling and therapy add-on code (HCPCS code G2080). We are also proposing that, following the conclusion of the PHE for COVID–19, when counseling or therapy services are furnished using audio-only telephone calls, either as part of a weekly bundle or billed using the counseling and therapy add-on code (HCPCS code G2080), OTPs would be required to document in the beneficiary's medical record that the counseling or therapy was furnished via audio-only telephone call and the rationale for doing so. In addition, we are proposing the use of a new service-level modifier to be appended to claims submitted for the counseling and therapy add-on code (HCPCS code G2080) when furnished via an audio-only interaction, which would serve to certify that the practitioner had the capacity to furnish the services using two-way, audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary. The use of this modifier would allow CMS to track utilization of this flexibility in the claims data and evaluate that data as we consider ongoing refinements to the OTP benefit in the future. To avoid placing additional burden on OTPs during the PHE for COVID–19, these proposed new requirements would take effect on January 1, 2022, but would apply only for services furnished after the conclusion of the PHE for COVID–19. Accordingly, if the PHE for COVID–19 extends into 2022, OTPs that furnish counselling and therapy services using either two-way audio/video technology or audio-only telephone calls would not be required to use the applicable modifier or to comply with the new documentation requirements until after the end of the PHE.

Accordingly, we are proposing to revise § 410.67(d) to add a new paragraph (6) to state that when substance use counseling under paragraph (b)(3) of this section or therapy services under paragraph (b)(4) of this section are furnished using audio-only telephone calls after the end of the PHE, as defined in § 400.200 of this chapter, the practitioner must document in the beneficiary's medical record that the services were furnished using audio-only technology and the rationale for doing so. For purposes of the add-on code for additional counselling and therapy services, the practitioner must also certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because the beneficiary did not have access to two-way audio/video communications technology. Under these proposals, we would defer to clinician judgment in determining whether in-person counseling or therapy, rather than the use of audio-only telephone calls, would be most appropriate in certain circumstances, such as for patients who are considered to be high risk. Additionally, we are seeking comment on whether we should put any additional or alternative conditions in place to promote program integrity, minimize patient safety concerns, and ensure that beneficiaries have access to the most appropriate form of care.

P. Physician Self-Referral Updates

1. The Physician Self-Referral Statute and Regulations

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act; see 66 FR 857 through 858.

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992

(related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was a final rule with comment period published in the January 4, 2001 **Federal Register** (66 FR 856). The second final rulemaking (Phase II) was an interim final rule with comment period (69 FR 16054) published in the March 26, 2004 **Federal Register**. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published in the April 6, 2004 **Federal Register** (69 FR 17933). The third final rulemaking (Phase III) was a final rule published in the September 5, 2007 **Federal Register** (72 FR 51012).

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the Fiscal Year (FY) 2009 Inpatient Prospective Payment System final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) Revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per unit of service (often referred to as ''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of ''entity.''

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. The new exception at § 411.357(y) for timeshare arrangements included a limitation on certain per unit of service and percentage-based compensation formulas. On November 15, 2016, in the CY 2017 PFS final rule, we again finalized requirements that the rental charges for the lease of office space or equipment are not determined using a formula based on per unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (81 FR 80534). The requirements are identical to those in effect since October 1, 2009, and are included in the exceptions for the rental of office space at § 411.357(a)(5)(ii)(B), the rental of equipment at § 411.357(b)(4)(ii)(B), fair market value compensation at § 411.357(l)(3)(ii), and indirect compensation arrangements at § 411.357(p)(1)(ii)(B).

In the December 2, 2020 **Federal Register**, we published a final rule entitled ''Modernizing and Clarifying the Physician Self-Referral Regulations'' (the ''MCR final rule'') (85 FR 77492) that established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as ''value-based arrangements,'' established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law. Most notably, we defined the term ''commercially reasonable'' in regulation, established an objective test for evaluating whether compensation varies with the volume or value of referrals or other business generated between the parties, and revised the definitions of ''fair market value'' and ''general market value.'' The MCR final rule also revised the definition of ''indirect compensation arrangement.''

2. Indirect Compensation Arrangements (§ 411.354(c)(2))

a. Summary of Proposals

We are proposing to revise the regulation at § 411.354(c)(2) that sets forth the conditions for the existence of an indirect compensation arrangement. First, we are proposing to revise § 411.354(c)(2)(ii), which identifies when aggregate compensation to a physician results in an indirect compensation arrangement (if the other conditions of § 411.354(c)(2) are met), to more precisely address the concerns and effectuate the policies that we articulated in the MCR final rule. Specifically, we are proposing to revise the regulation to include as a potential indirect compensation arrangement any unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves compensation for anything other than services that he or she personally performs. This would include arrangements for the rental of office space or equipment that meet the other conditions of the regulation at § 411.354(c)(2), which would be subject to, among other requirements, the prohibition on percentage-based and unit-based (often referred to as ''per-click'') compensation formulas at § 411.357(p)(1)(ii) in the exception for indirect compensation arrangements (or the requirements of another applicable exception). Second, following the publication of the MCR final rule, we received inquiries from stakeholders requesting clarification on the term ''unit'' in § 411.354(c)(2)(ii)(A). We are proposing to define the term ''unit'' for purposes of applying the regulation. We are also proposing to define ''services that are personally performed'' for purposes of applying proposed § 411.354(c)(2)(ii)(A)(4).

b. Definition of ''Indirect Compensation Arrangement''

Although section 1877(h)(1) of the Act defines the term ''compensation arrangement'' as including both direct and indirect compensation, the statute does not define the term ''indirect compensation arrangement.'' In Phase I, relying on the Secretary's authority under section 1877(b)(4) of the Act, we set forth in regulation the conditions under which an indirect compensation arrangement exists and a corresponding exception for such arrangements (66 FR 684 through 687). In Phase II, we revised the regulation at § 411.354(c)(2)(ii) to distinguish the language identifying when an indirect

compensation arrangement exists from the language of the exception for indirect compensation arrangements at § 411.357(p) (69 FR 16069). Most recently, in the MCR final rule, we further revised the regulation at § 411.354(c)(2) that identifies when an indirect compensation arrangement exists (85 FR 77544 through 77546).

Prior to the MCR final rule, an unbroken chain of financial relationships between a referring physician (or a member of his or her immediate family) and the entity furnishing designated health services established an ''indirect compensation arrangement'' if all the elements of § 411.354(c)(2), as then in effect, existed. The indirect compensation arrangement must satisfy the requirements of an applicable exception in order to avoid the referral and billing prohibitions of the physician self-referral law. (In the alternative, the parties could use an exception at § 411.355 to except the physician's referrals on a service-by-service basis.) This two-step process, which first identified the universe of unbroken chains of financial relationships that might be of concern and then excepted from the physician self-referral law's prohibitions those unbroken chains of financial relationships that did not pose a risk of program or patient abuse, was developed to closely correspond to the statutory treatment of compensation arrangements directly between an entity and a referring physician (or an immediate family member of the referring physician) (69 FR 16059). When analyzing compliance with the requirement that compensation does not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity, which is included in the exception for indirect compensation arrangements at § 411.357(p) and certain exceptions for direct compensation arrangements, special rules on unit-based compensation at § 411.354(d)(2) and (3) that deemed certain compensation not to take into account the volume or value of the physician's referrals or the other business generated by the physician could be applied.

As noted above, in the MCR final rule, we established an objective test for evaluating whether compensation varies with the volume or value of referrals or other business generated between the parties and responded to commenters that questioned whether compensation to a physician would run afoul of the objective tests under specified circumstances (85 FR 77539 through 77547). Inquiring about proposed modifications to § 411.354(c)(2)(ii) that we did not ultimately finalize, one commenter presented the example of a physician who performs surgeries at a hospital and receives a fixed amount per personally-performed relative value unit that is consistent with the fair market value of the physician's services (85 FR 77544). In developing our response to the commenter (and other commenters), we revisited the regulatory construct for determining which unbroken chains of financial relationships between entities and physicians (or immediate family members of physicians) establish indirect compensation arrangements and how to determine if they pose a risk of program or patient abuse (85 FR 77545).

With the underlying goal of reducing unnecessary burden on providers and suppliers, we stated that we do not see a need to treat compensation arrangements that may qualify as ''indirect compensation arrangements'' in the exact same way that the statute treats direct compensation arrangements when that construct creates unnecessary burden on the regulated industry (85 FR 77545 through 77546). We stated that it is possible to simplify the analysis of whether an unbroken chain of financial relationships presents a risk of patient or program abuse or poses program integrity concerns (85 FR 77546), and finalized revisions to § 411.354(c)(2) intended to achieve the same result as the two-step Phase I regulatory construct in protecting against program or patient abuse while reducing unnecessary burden on the regulated industry (88 FR 77546). The revised (now current) regulation at § 411.354(c)(2)(ii) effectively incorporates and applies the conditions of the special rules on unit-based compensation at § 411.354(d)(2) and (3) at the definitional level when determining whether there exists an indirect compensation arrangement that must satisfy the requirements of an applicable exception in order to avoid the prohibitions of the physician self-referral law.

Under the regulation finalized in the MCR final rule, an unbroken chain of financial relationships between an entity and a physician is considered an indirect compensation arrangement if the physician (or immediate family member of the physician) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing the designated health services, and any of the following are true: (1) The individual unit of compensation received by the physician (or immediate family member) is not fair market value for items or services actually provided; (2) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or (3) the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity. In addition, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity. Under the regulation, unless all the elements of § 411.354(c)(2)(i), (ii), and (iii) exist, an unbroken chain of financial relationships between an entity furnishing designated health services and a physician (or immediate family member of a physician) is not considered an indirect compensation arrangement.

As explained previously, the changes to the regulations that identify indirect compensation arrangements of concern under the physician self-referral law occurred in response to comments and inquiries primarily in the context of compensation paid to physicians for their personally performed services (85 FR 55739 through 55747). The revisions to § 411.354(c)(2)(i) through (iii) were intended to more precisely identify arrangements that pose a risk of overutilization, patient steering, and other abusive conduct at an earlier stage of the analysis (85 FR 77546). However, in streamlining the former two-step process for analyzing unbroken chains of financial relationships, we inadvertently omitted an important program integrity requirement that previously applied when determining satisfaction of the requirements of the

exception at § 411.357(p) for indirect compensation arrangements. As a result, we inadvertently excluded from the definition of ''indirect compensation arrangement'' a subset of unbroken chains including compensation arrangements that we have long identified as presenting significant program integrity concerns: Certain arrangements involving unit of service-based payment for the rental of office space or equipment.

We have repeatedly stated our view that unit of service-based compensation formulas in arrangements for the lease of space and equipment are inherently susceptible to abuse because the physician lessor has an incentive to profit from referring a higher volume of patients to the lessee. Beginning with the 1998 proposed rule, we stated that unit of service-based payments for patients who are referred for the service by the lessor physician were not consistent with the requirement that compensation not reflect the volume or value of a physician's referrals or other business generated (63 FR 1714). In Phase I, we revisited the issue, reviewed the legislative history, and concluded that, as long as the per-unit payment reflected fair market value in arms' length bargaining and did not vary over the course of the arrangement, unit of service-based payments could qualify for the protection of an exception, provided that the other requirements of the applicable exception are met. (66 FR 876). We noted that such arrangements might run afoul of the anti-kickback statute and stated our intent to continue to monitor such arrangements for potential abuse (66 FR 878).

Subsequently, in the 2009 IPPS final rule, based on our observations of program integrity concerns and comments in support of prohibiting unit of service-based compensation formulas in office space and equipment leases, we finalized revisions to the exceptions for the rental of office space at § 411.357(a), the rental of equipment at § 411.357(b), fair market value compensation at § 411.357(l), and indirect compensation arrangements at § 411.357(p). The revised exceptions required that, to the extent that such arrangements related to the lease of office space or equipment, the rental charges may not be determined using a formula based on: (1) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the service performed or business generated in the office space; or (2) unit of service-based rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (73 FR 48713 through 48714). Commenters largely supported the change. A significant number of commenters reported their own experiences of situations in which unit of service-based compensation arrangements resulted in patients being referred for medically unnecessary treatment. Some hospitals reported being effectively compelled to lease equipment from physician groups (73 FR 48715). In the 2016 PFS final rule, we included similar restrictions on percentage-based and unit of service-based compensation formulas in the new exception at § 411.357(y) for timeshare arrangements. In support of that limitation, we again cited concerns that unit of service-based compensation formulas in arrangements involving the use of office space or equipment could lead to overutilization and patient steering (80 FR 71331 through 71332).

We most recently addressed the issue of unit of service-based compensation formulas in depth in the 2017 PFS proposed and final rules. In those rules, at the direction of the D.C. Circuit Court in *Council for Urological Interests* v. *Burwell,* 790 F.3d 212 (D.C. Cir. 2015), we explained our rationale for the restrictions as they apply to arrangements for the lease or use of office space or equipment, again identifying overutilization and patient steering as the primary program integrity concerns supporting our conclusion that such compensation provisions present a significant program risk (81 FR 46452 through 46453 and 80528 through 80534). We reiterated that unit of service-based compensation formulas, in particular in arrangements for the lease of equipment:

- Create an incentive for overutilization of imaging services (as described by MedPAC in its comments to our proposal in the CY 2008 PFS proposed rule), as well as other services, including therapeutic services;
- Create an incentive for physicians to narrow their choice of treatment options to those for which they will realize a profit, even where the best course of action may be no treatment;
- Influence physicians to refer to the lessee instead of referring to another entity that utilizes the same or different (and perhaps more efficacious) technology to treat the patient's condition;
- Result in physicians steering patients to equipment they own, even if it means having the patient travel to a non-convenient site for services using the leased equipment; and
- Increase costs to the Medicare program when referring physicians pressure hospitals to use their leasing company despite not being the low cost provider.

We also identified two advisory opinions issued by OIG in which OIG voiced concerns about unit of service-based compensation arrangements and indicated that such arrangements are disfavored under the anti-kickback statute (81 FR 80528). Commenters again were largely supportive of the proposal, which merely re-proposed the then-existing prohibitions on such compensation formulas in arrangements for the lease or use of office space or equipment (81 FR 80528 through 80529).

Our position on the inherent risks presented by unit of service-based compensation formulas in the context of the rental of space or equipment has not changed since the 2017 PFS final rule. This fact is evident elsewhere in the MCR final rule. For example, the rule finalized changes to the exception for fair market value items and services, making it applicable to the rental of office space (85 FR 77606). With this change, we also revised the exception to state that the previously-established restrictions at § 411.357(l)(3)(i) and (ii) applicable to fair market value equipment leases also apply to leases of office space. We reiterated our longstanding concerns with unit of service-based compensation formulas for leases of office space and equipment, described the history of such concerns, and stated, in response to a comment supporting the inclusion of the restriction, that it was ''a necessary safeguard'' for the reasons articulated in our prior rulemakings (85 FR 77607). We included a similar restriction in the newly-finalized exception for limited remuneration to a physician at § 411.357(z), citing the same concerns (85 FR 77624).

We continue to believe that arrangements involving unit of service-based compensation for the rental of office space or equipment, whether direct or indirect, may pose a significant risk of program abuse, and are proposing revisions to § 411.354(c)(2)(ii) that would ensure that the prohibition on certain unit of service-based compensation formulas for the rental of office space or equipment applies to all compensation arrangements that include them. Under proposed § 411.354(c)(2)(ii), an unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member) is an arrangement for the rental of office space or equipment would be an indirect compensation arrangement if all other conditions of § 411.354(c)(2)(i) through (iii) are met. If

the parties to the compensation arrangement elect to use the exception at § 411.357(p) instead of another applicable exception, if any, the compensation for the rental or office space or equipment may not be determined using a formula based on per-unit of service rental charges to the extent that such charges reflect services provided to patients referred by the lessee to the lessor.

Arrangements involving compensation to a physician for items or the services of others where the physician's referral of designated health services to an entity or other business generated by the physician for an entity may contribute to the compensation received by the physician are distinguishable from arrangements that solely involve compensation for a physician's personally performed services. Program integrity concerns arise when payment for items or services provided as the result of a physician's referrals or the other business the physician generates, rather than the physician's own labor, is included in the calculation of compensation. As discussed previously, the MCR final rule policy that identifies indirect compensation arrangements of concern under the physician self-referral law in a single-step process was focused on reducing unnecessary burden related to the analysis of unbroken chains of financial relationships that do not pose a risk of program or patient abuse, and was developed in the context of compensation paid to physicians for their personally performed services. However, the current regulations, as finalized in the MCR final rule, are not limited to indirect compensation arrangements under which a physician (or immediate family member) is paid solely for services that he or she personally performs, which, as a general matter, do not raise significant program integrity concerns, provided that the compensation is consistent with fair market value for the personally performed services.

To better align with our view regarding the reduced risk of program or patient abuse where compensation to a physician (or an immediate family member of a physician) is solely for services that he or she personally performs, the proposed revisions to § 411.354(c)(2)(ii) would require a two-step analysis of any unbroken chain of financial relationships in which the compensation paid under the arrangement closest to the physician (or immediate family member) is for anything other than services personally performed by the physician (or immediate family member), including, as noted above, arrangements for the rental of office space or equipment. Specifically, we are proposing to revise the condition at § 411.354(c)(2)(ii)(A) to consider an unbroken chain of financial relationships between a physician and an entity that meets the other conditions of § 411.354(c)(2)(i) through (iii) to be an indirect compensation arrangement for purposes of the physician self-referral law if the unit of compensation received by the physician (or immediate family member) is payment for anything other than services personally performed by the physician (or immediate family member). We are also proposing slight revisions to the language of § 411.354(c)(2)(ii)(A)(*2*) and (*3*) to clarify that these conditions relate to the formula for calculating of the amount of compensation per unit. As proposed, the condition at § 411.354(c)(ii)(A) would state that the referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the designated health services and the individual unit of compensation received by the physician (or immediate family member): (1) Is not fair market value for items or services actually provided; (2) Is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation that positively correlates with the number or value of the physician's referrals to the entity; (3) Is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation per unit that positively correlates with the physician's generation of other business for the entity; or (4) Is payment for anything other than services personally performed by the physician (or immediate family member). For purposes of proposed § 411.354(c)(2)(ii)(A)(*4*), we would consider services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member) not to be personally performed by the physician. We are proposing to codify this policy at § 411.354(c)(2)(ii)(B)(3).

c. Definition of ''Unit'' for Purposes of Applying § 411.354(c)(ii)(A)

As explained above, under current § 411.354(c)(2)—which was finalized in the MCR final rule—the determination of whether an indirect compensation arrangement exists requires the evaluation of the individual unit of compensation that the physician (or immediate family member) receives. If the individual unit of compensation does not meet any of the conditions at § 411.354(c)(2)(ii)(A)(*1*) through (*3*), the unbroken chain of financial relationships does not constitute an indirect compensation arrangement. Since the publication of the MCR final rule, we have received inquiries from stakeholders regarding how the provisions of § 411.354(c)(2)(ii)(A) should be applied in situations where compensation does not appear to be unit-based or is calculated using two or more different units or types of units. We are proposing revisions to § 411.354(c)(2)(ii)(B) to clarify how to identify the unit to analyze against the conditions of current § 411.354(c)(2)(ii)(A)(*1*) through (*3*) and proposed § 411.354(c)(2)(ii)(A)(*4*).

As a preliminary matter, it is our position that all compensation essentially is unit-based compensation. The underlying unit may be a discrete item, a unit of service, a unit of time, or a unit that results from combining different types of units into a single unit used to calculate the compensation. The identification of purely time-based or service-based units is straightforward. With respect to compensation that is entirely paid per hour, per day, per month, per year, or per similar period of time, the individual unit of compensation is the smallest unit of time for which the compensation is paid. For example, where a physician is paid $150 per hour for his or her medical director services, the unit is an hour. Similarly, where a physician is paid $350,000 per year for his or her full-time professional services, the unit is a year. With respect to compensation that is entirely paid per service, such as a work relative value unit (wRVU) or the provision of a training seminar, the unit is the individual service. For example, where a physician is paid $30 per wRVU that he or she personally performs, the unit is a wRVU. Similarly, where a physician is paid $1000 to provide a training session on infection control measures for an organization's employees, the unit is a training session.

Compensation formulas that incorporate a percentage of a variable are also unit-based. For example, if a physician is paid 50 percent of the amount collected for the professional services that he or she performs in a calendar year, the unit is a calendar year. If a physician is paid 95 percent of the Medicare PFS amount for a particular service that he or she personally performs, the unit is the service.

We are aware that compensation arrangements may include different units of compensation paid to a physician. According to stakeholders inquiring about the application of § 411.354(c)(2)(ii)(A), a physician employed by a physician organization may receive an annual salary for his or her full-time professional services furnished to patients of the physician organization plus a productivity bonus for each wRVU that he or she personally performs. The stakeholders inquired how to identify the unit that results from combining different types of units into a single unit used to calculate the physician's compensation. In such instances, we consider the unit of compensation to be time-based and reflect the aggregate compensation paid to the physician during the period of time applicable to the payment; that is, the time-period during which compensation is paid (for example, per month or per year) or over the entire term of the arrangement. It is our understanding that fair market valuations generally follow this construct, determining the fair market value of various types of compensation for a physician's personally performed services, such as fixed salary payments and productivity or bonus compensation, by assessing the physician's compensation in the aggregate over a period of time. Further, a service-based unit of compensation is easily converted to a time-based unit by incorporating the period of time applicable to the payment for the services (for example, $30 per wRVU *per month*), while the reverse is not true. It is for these reasons that we believe that ''hybrid'' compensation—that is, compensation that has both a time-based unit component and a service-based unit component—is appropriately analyzed by converting it to compensation for a unit of time for purposes of applying § 411.354(c)(2)(ii).

To illustrate, assume that an employment arrangement between a physician and a physician organization specifies compensation of $200,000 per calendar year for the physician's full-time professional services plus a productivity bonus of $10 for each wRVU that he or she personally performs, and that the physician is paid on a monthly basis. The unit of compensation would be a month, and the formula for determining the compensation per month would be ($200,000 ÷ 12 months) + ($10 × the number of wRVUs personally performed during the month). (In the alternative, the parties could analyze the arrangement under § 411.354(c)(2)(ii)(A) using a calendar year as the unit of compensation.) However, if the employment arrangement specified productivity bonus compensation of $10 per wRVU only for those personally performed wRVUs above a predetermined target, the unit would be the period of time for which the target is applicable. To illustrate, instead of $10 for each wRVU that the physician personally performs, assume that the physician receives $10 for the wRVUs that he or she personally performs in excess of 4,000 wRVUs per calendar year. The unit of compensation would be a calendar year, and the formula for determining the compensation per year would be $200,000 + $10 × (actual number of wRVUs personally performed during the calendar year − 4,000).

We note that a compensation arrangement may also involve multiple units of the same type. For example, a physician employed by a physician organization may receive a salary of $200,000 per year for his or her full-time professional services plus $150 per hour for his or her personally performed medical director services or $500 per month for each of the physician organization's NPPs that he or she supervises. Or, a physician may receive compensation for services based on a fee schedule; for example, $50 for service A, $75 for service B, and $100 for service C. In circumstances where more than one unit of the same type is used to calculate the physician's compensation, each unit must be analyzed under § 411.354(c)(2)(ii)(A)(*1*) through (*4*) to determine whether the conditions for an indirect compensation arrangement exist.

To facilitate compliance with the physician self-referral law as it applies to indirect compensation arrangement, we are proposing a new regulation at § 411.354(c)(2)(ii)(B)(*2*) that expressly identifies the unit to consider for purposes of applying the regulation at § 411.354(c)(2)(ii)(A) and determining the existence of an indirect compensation arrangement that must satisfy the requirements of an applicable exception. Under proposed § 411.354(c)(2)(ii)(B)(*2*), for purposes of applying § 411.354(c)(2)(ii)(A), the individual unit is: (1) Time, where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the services are provided; (2) service, where the compensation paid to the physician (or immediate family member) is based solely on the service provided; and (3) time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided.

We seek comment on the proposals discussed above and whether additional guidance is needed with respect to the determination of whether an indirect compensation arrangement exists.

3. Exception for Preventive Screening Tests, Immunizations, and Vaccines (§ 411.355(h))

As a general matter, vaccines fall within the definition of ''outpatient prescription drugs'' at § 411.351, and therefore, are considered designated health services for purposes of the physician self-referral law. Because the federal government purchased the initial supply of COVID–19 vaccines, Medicare does not make payment for COVID–19 vaccines at this time,[123] and COVID–19 vaccines do not fall within the definition of ''designated health service'' at § 411.351. However, should COVID–19 vaccines become payable by Medicare, unless the requirements of an applicable exception to the physician self-referral law are satisfied, the physician self-referral law's prohibitions under section 1877(a)(1) of the Act and § 411.353(a) and (b) would apply to the referral and billing of COVID–19 vaccines.

In Phase I, using the Secretary's authority at section 1877(b)(4) of the Act to create additional exceptions that do not pose a risk of program or patient abuse, we finalized an exception at § 411.355(h) that excludes from the physician self-referral law's referral and billing prohibitions certain preventive screening tests, immunizations, and vaccines covered under Medicare (66 FR 939). As finalized in Phase I, in addition to requirements related to compliance with the federal anti-kickback statute and federal and state laws and regulations related to billing and claims submission, the exception at § 411.355(h) required that the preventive screening test, immunization, or vaccine is subject to CMS-mandated frequency limits, reimbursed by Medicare based on a fee schedule, and listed on the CMS website

[123] See *https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.*

and in annual PFS Updates. In Phase II, we removed the requirement that the preventive screening test, immunization, or vaccine is reimbursed based on a fee schedule, in recognition that some of the vaccines eligible for the exception may be paid by Medicare using different reimbursement methods (69 FR 16116). In the MCR final rule, as part of a broader effort to decouple the physician self-referral law from the federal anti-kickback statute and federal and state laws or regulations governing billing or claims submission, we removed the requirement at former § 411.355(h)(2) that the arrangement does not violate the federal anti-kickback statute as well as the requirement at former § 411.355(h)(3) that the arrangement does not violate any federal or state law or regulation governing billing or claims submission (85 FR 77567).

Services to which the exception at § 411.355(h) is applicable remain designated health services for purposes of the physician self-referral law; however, referrals may be made and claims submitted for such services if all requirements of the exception are satisfied (69 FR 16100). In the CY 2021 PFS final rule, we added COVID–19 vaccines to the list of immunization and vaccine codes to which the exception at § 411.355(h) is applicable (85 FR 84954 through 85955). We did so to ensure that the physician self-referral law would not impede the availability of COVID–19 vaccines for Medicare and other patients if they become payable by Medicare (85 FR 84955).

Under current § 411.355(h)(1), a preventive screening test, immunization, or vaccine must be subject to CMS-mandated frequency limits, among other requirements. Frequency limits determine the maximum number of times that Medicare will pay for a service for a particular beneficiary during an established period, often a calendar year or 12-month period. CMS-mandated frequency limits also serve to minimize the risk of program or patient abuse due to a physician's financial self-interest because Medicare would not pay for additional services referred and furnished in excess of the frequency limitation. In Phase I, we stated our belief that, under the terms of the exception at § 411.355(h) as finalized in Phase I—which included the requirement that the service is subject to CMS-mandated frequency limits—the risk of abuse is extremely low. We also stated that the exclusion of certain preventive screening tests, immunizations, and vaccines from the reach of the physician self-referral law is consistent with the statutory language and structure and the expressed Congressional intent to provide preventive care to Medicare beneficiaries (66 FR 939).

The United States continues to respond to the outbreak of COVID–19 caused by the severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2). At this time, we have not mandated frequency limits for the COVID–19 vaccines identified on the List of CPT/HCPCS Codes (Code List) to which the exception at § 411.355(h) is applicable and we are uncertain whether or, if so, when CMS may mandate frequency limits for COVID–19 vaccines. Thus, although COVID–19 vaccines are identified on the List of CPT/HCPCS Codes as codes to which the exception at § 411.355(h) is applicable, they would not satisfy the requirement at current § 411.355(h)(1) that the preventive screening test, immunization, or vaccine is subject to CMS-mandated frequency limits. We are concerned that the current absence of CMS-mandated frequency limits on the available COVID–19 vaccines could impede the availability of critically important COVID–19 vaccines for Medicare and other patients, as physician referrals for COVID–19 vaccines would be prohibited unless another exception to the physician self-referral law is applicable and all its requirements are satisfied. Therefore, we are proposing to permit the use of the exception at § 411.355(h) for COVID–19 vaccines even when they are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. Specifically, we are proposing to revise and renumber the regulation at § 411.355(h). Revised § 411.355(h)(1) would include the conditions that must be met to avoid the physician self-referral law's referral and billing prohibitions, and revised § 411.355(h)(2) would state that the requirement at § 411.355(h)(1)(iii) does not apply to a COVID–19 vaccine code during such period that the vaccine is not subject to a CMS-mandated frequency limit. In light of the impact of the COVID–19 pandemic on the United States and the vital need to protect beneficiaries (and others) from the SARS-CoV–2 virus, we do not believe that making the exception at § 411.355(h) available for COVID–19 vaccines to which no CMS-mandated frequency limits apply would pose a risk of program or patient abuse. We seek comment on our approach and whether we should limit relief from the requirement at proposed § 411.355(h)(1)(iii) to the period during which the current public health emergency is in effect, until such time as CMS-mandated frequency limits apply for COVID–19 vaccines, or some other period of time.

In the alternative, we are proposing to remove the CMS-mandated frequency limit requirement for all vaccines. We seek comment on whether it would then be necessary to include alternative program integrity requirements in the exception at § 411.355(h). We are interested in comments regarding whether physicians are likely to order vaccines more frequently than recommended by the Department and any other organization the Department identifies as an authority on this matter.

We are not proposing to remove the CMS-mandated frequency limit requirement with respect to preventive screening tests. We remain concerned that a physician's ability to refer frequently for preventive screening tests could lead to program or patient abuse, and do not believe that the current COVID–19 pandemic or any other circumstances necessitate the removal of this important program integrity protection with respect to preventive screening tests.

We are also proposing to revise the terminology used in the exception at § 411.355(h) for clarity and consistency. Specifically, we are proposing to remove the terms ''immunization'' and ''immunizations'' throughout § 411.355(h) and the headers used in the Code List. The Centers for Disease Control and Prevention (CDC) defines immunization as a process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation. Vaccine is defined as a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease.[124] All of the codes currently on the Code List to which the exception at § 411.355(h) is applicable have a descriptor containing ''vaccine'' or a derivative of ''vaccine.''

Vaccines fall within the definition of ''outpatient prescription drugs'' at § 411.351, and therefore, are considered designated health services for purposes of the physician self-referral law. As defined by the CDC, an immunization is not an item or service that is a ''designated health service'' (as defined in § 411.351) and to which the physician self-referral law applies. We believe that ''vaccine'' is the appropriate term to use in § 411.355(h) and in the

[124] *https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm.*

headers in the Code List. Although we are not aware that including both terms in § 411.355(h) and the Code List has caused stakeholder confusion to date, we are proposing to improve the accuracy of the terminology at this time to prevent any possible confusion in the future. The proposed revisions to § 411.355(h), if finalized, would not affect whether we consider a code to be a designated health service.

4. List of CPT/HCPCS Codes (§ 411.351)

As described in section III.P.1. of this proposed rule, unless an exception applies and its requirements are satisfied, the physician self-referral law prohibits a physician from making a referral for the furnishing of certain designated health services if the physician has a financial relationship with the entity to which the referral is made. Recognizing that providing precise definitions of which designated health services implicate the physician self-referral law would facilitate compliance with the law, in the Phase I final rule, we determined to define certain designated health services by publishing specific lists of CPT and HCPCS codes that physicians and providers most commonly associate with a given designated health service (66 FR 922). This list of codes defines the entire scope of the designated health services category for purposes of the physician self-referral law and is controlling vis-à-vis the definition of the category at § 411.351, which contains a general explanation of the principles used to select the codes.

In Phase I, we stated that, because HCPCS Level I and II codes change and can quickly become out-of-date, we would not include the list of codes that are designated health services in the text of our regulations (66 FR 923). We also stated that, the definitions of specific services in our regulations would cross refer to a comprehensive table that would appear initially in the **Federal Register** along with Phase I and thereafter in an addendum to the annual final rule concerning payment policies under the PFS rule. We defined at § 411.351 the term ''List of CPT/HCPCS Codes Used to Describe Certain Designated Health Services Under the Physician Referral Provisions (Section 1877 of the Social Security Act)'' to mean the list of certain designated health services under section 1877 of the Act initially posted on the CMS website and updated annually thereafter in an addendum to the PFS final rule and on the CMS website. In the Phase II interim final rule, we revised the term to ''List of CPT/HCPCS Codes'' and its definition to ''the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act.'' The Phase II definition also stated that the list is updated annually, as published in the **Federal Register**, and is posted on the CMS website at *http://www.cms.gov/medlearn/refphys.asp*. Other than including an updated URL for the location of the list on the CMS website, the current definition of List of CPT/HCPCS Codes is identical to the Phase II definition. The CMS website currently identifies this list as the Code List for Certain Designated Health Services (the Code List).[125]

Coding changes have become more frequent since we initially began publishing the Code List. Currently, CPT codes are updated annually and effective for use on January 1 of each year, with some exceptions for Category I, II, and III codes, which are published more frequently. CMS has updated its HCPCS Level II coding procedures to enable shorter and more frequent HCPCS coding cycles. For example, we have implemented quarterly HCPCS code application opportunities for drugs and biologicals; and bi-annual application opportunities for Durable Medical Equipment (DME) and Orthotics, Prosthetics (O&P), and Supplies, as part of our comprehensive initiative to foster innovation and expedite adoption of and patient access to new medical technologies. (See *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo*.)

In order to make available the most recent updates in a timelier manner for purposes of the physician self-referral law, we are proposing to update the Code List on a more frequent basis. Specifically, we are proposing to update the Code List each calendar quarter, and provide public notification in advance of Code List updates. Advance notification would be posted on the CMS website on March 1, June 1, September 1, and December 1 of each year, with corresponding Code List updates effective on April 1, July 1, October 1, and January 1, respectively. We are also proposing a 30-day public comment period following the posting of each advance notification of the upcoming quarterly Code List update. Under this proposal, we would provide information on our website regarding the process for submitting public comments through *www.regulations.gov* and address all public comments on the Code List on the CMS website. We anticipate that most comments would be addressed within 90 calendar days of the effective date of the Code List update to which they pertain; however, a longer timeframe may be necessary to address complex comments or those that require coordination with external parties. This new process and schedule would begin with the update effective April 1, 2022. The Code List that is effective January 1, 2022 would be included in the CY 2022 PFS final rule. We believe that predetermined dates for the updates will provide clarity and transparency for stakeholders regarding any revisions to the Code List.

In addition, we are proposing to publish the Code List solely on the CMS website (commencing after the publication of the January 1, 2022 Code List in the CY 2022 PFS final rule, as proposed above). We believe that publication via the CMS website would facilitate compliance with the physician self-referral law and allow access to the most up-to-date Code List. Further, this approach would provide a more comprehensive list of codes identifying designated health services for purposes of the physician self-referral law that better aligns with the current coding cycles for CPT and HCPCS codes.

Finally, we are proposing corresponding revisions to the definition of List of CPT/HCPCS Codes at § 411.351 to update the URL that indicates where the Code List is published on the CMS website. Specifically, we are proposing to revise the definition of List of CPT/HCPCS Codes at § 411.351 to state ''*List of CPT/HCPCS Codes* means the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated each calendar quarter and posted on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes*.''

We seek comment on our proposals and whether more or less frequent Code List updates would be appropriate.

Q. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. SUPPORT Act Requirements

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program

[125] *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

beginning January 1, 2021, subject to exceptions, which the Secretary may specify. Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the Electronic Prescribing for Controlled Substances (EPCS) requirement, and provides the Secretary with authority to enforce and specify appropriate penalties for non-compliance with EPCS. The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and permits HHS to develop other appropriate exceptions. Since the statute states that the Secretary shall through rulemaking specify circumstances and processes by which the Secretary ''may waive'' the EPCS requirement, we consider the list to be illustrative. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are at section 1860D–4(e)(7) of the Act, as added by section 2003 of the SUPPORT Act, and include:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;
- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT standard, which is the SCRIPT 2017071 standard;
- A prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed 1 year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;
- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;
- A prescription issued by a practitioner prescribing a drug under a research protocol;
- A prescription issued by a practitioner for a drug for which the FDA requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;
- A prescription issued by a practitioner—

++ For an individual who receives hospice care under title XVIII of the Act; and

++ That is not covered under the hospice benefit under title XVIII of the Act; and

- A prescription issued by a practitioner for an individual who is—

++ A resident of a nursing facility (as defined in section 1919(a) of the Act); and

++ Dually eligible for benefits under title XVIII and title XIX of the Act.

2. Previous Regulatory Action

To begin the process of implementing section 2003 of the SUPPORT Act, in August 2020, we released a Request for Information entitled ''Medicare Program: Electronic Prescribing of Controlled Substances; Request for Information (RFI)'' (85 FR 47151) (hereinafter referred to as the August 2020 RFI). In August 2020, we released the CY 2021 PFS proposed rule (85 FR 50074) (hereinafter referred to as the CY 2021 PFS proposed rule), which proposed that Part D prescribers be required to use the NCPDP SCRIPT 2017071 standard for EPCS prescription transmissions. We proposed that this mandate would not become effective until January 1, 2022.

We received a combined total of 155 timely comments in response to the August 2020 RFI and the CY 2021 PFS proposed rule. Most commenters supported implementing EPCS and use of the NCPDP SCRIPT 2017071 standard. Comments were mixed as to when compliance actions for EPCS should begin. Some commenters requested that CMS adhere to the January 1, 2021 date specified in the SUPPORT Act because of the many safety benefits associated with EPCS articulated in the rule. Some prescriber groups supported the proposed January 1, 2022 date, while others requested even more time for implementation. To balance the needs of prescribers who wanted more time to implement EPCS and commenters who wanted adherence to the January 1, 2021 date, we finalized this provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022 in the CY 2021 Physician Fee Schedule final rule (85 FR 84472) (hereinafter referred to as the CY 2021 PFS final rule). Due to the consensus among commenters that the NCPDP SCRIPT 2017071 standard was the best choice for EPCS, we required in the CY 2021 PFS final rule that Part D prescribers use this standard.

3. Current EPCS Environment

A variety of Part D medications are classified as controlled substances by the Drug Enforcement Administration (DEA). Among these are medications used for the treatment of acute and chronic pain, (for example, hydrocodone, fentanyl, codeine, methadone), and stimulant medications (for example, Adderall®, Ritalin®). Buprenorphine (for example, Suboxone®) is one of only three of the most effective drugs approved by the FDA to treat opioid use disorders (OUD) including in outpatient settings, and is a Schedule III drug. Benzodiazepines and sedative-hypnotics (including Xanax®, Valium®, Ativan®, Restoril®, Midazolim®, and Halcion®) are used for sleep, agitation, and seizure disorders. Anabolic steroids (for example, Depo-testosterone®) are used to treat impotence, delayed puberty, hormonal imbalance, and inoperable breast cancers.

As discussed in the CY 2021 PFS proposed and final rules, we noted that electronic prescribing of controlled substances provides multiple advantages over the traditional processing of paper prescriptions. These advantages include, but are not limited to, improved workflow efficiencies; deterring and detecting prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes; enhanced patient safety through patient identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions; and providing more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of prescriptions for controlled substances between prescribers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. EPCS can also assure prescribers' identity more easily and may permit a single workflow for prescribing both controlled and non-controlled drugs, improving the overall prescribing process.

From the patient standpoint, EPCS may reduce the logistical burden on patients and caregivers who may

otherwise be required to make multiple trips between prescribers and pharmacies to transport paper prescriptions when filling time-sensitive prescriptions, while in pain, or otherwise in need of medical treatment with controlled substances. EPCS can lessen the time needed to obtain prescriptions by minimizing trips to the prescriber to pick up paper prescriptions for refills and minimize transportation costs to and from the prescriber's office. EPCS's identity and security requirements assure prescribers, patients, and pharmacies that prescriptions are processed as intended. In addition to helping with the reduction in fraud previously described, EPCS minimizes the likelihood that prescriptions have been tampered with, since electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, which minimizes the likelihood of exposure to patients or other third parties. During the PHE for COVID–19, EPCS also helps parties observe social distancing.

It is due to these advantages, coupled with the SUPPORT Act's EPCS mandate, that we encourage all prescribers to conduct EPCS as soon as is feasible for them. We believe that although EPCS is ultimately more efficient, implementing EPCS does take additional time and resources. Prescribers must follow DEA guidance for EPCS, which is summarized at *https://deadiversion.usdoj.gov/ecomm/e_rx/*. Prescribers must first ensure that their current ePrescribing software can support EPCS and meets DEA requirements pursuant to 21 CFR part 1311. Further, DEA also requires prescribers to have their identities verified prior to being issued the authentication credentials needed to sign and issue electronic controlled substance prescriptions. For individual prescribers, identity proofing (that is, verification that the prescriber is who he or she claims to be) is conducted by a credential service provider (CSP) or certification authority (CA). Institutional practitioners, as defined under 21 CFR 1300.01, have the option of conducting in-house identity proofing of the practitioners authorized to use the institution's e-prescribing software. Alternatively, institutional practitioners may require their practitioners to undergo identity proofing by a CSP or CA. Once their identities have been confirmed, prescribers may be issued their authentication credentials. The authentication credentials must be two-factor, meaning that prescribers must be required to supply two factors to confirm both their identity and their authorization to access the e-prescribing software. The factors may be something the prescriber knows (such as a password or PIN), something the prescriber has (such as a smartcard or token), or a biometric (such as a fingerprint). For institutional practitioners, the authentication credentials may be issued by an entity within the institution that is separate from the entity that conducted identity proofing, if identity proofing was conducted in-house. Otherwise, authentication credentials are issued by a CSP or CA. Once a prescriber has received his or her two-factor authentication credentials, the prescriber must be granted access to sign and issue electronic controlled substance prescriptions using the e-prescribing software. This step is completed by certain individuals specifically designated to manage the e-prescribing software's logical access controls. Prior to granting a prescriber access, the individuals managing logical access controls must verify that the prescriber's state authorization to practice and, where applicable, state authorization to prescribe controlled substances, are valid. Additionally, for individual prescribers (those prescribers not prescribing under an institutional practitioner's DEA registration), the individuals managing logical access controls must verify that their DEA registration is valid. This step is required even if they are already prescribing controlled substances on paper. After being granted access, practitioners may sign and issue electronic prescriptions for controlled substances using their two-factor authentication credentials. The EPCS application must require two-factor authentication for each transaction. Software and workflow training is available for each step of the process. When writing prescriptions, the prescriber may wish to talk with the patients and/or caregivers about electronic prescribing, so there is awareness of the general mechanics of how the prescription(s) will be conveyed to the pharmacy.

We recognize that section 2003(c) of the SUPPORT Act tasked the Department of Justice (DOJ) with updating the requirements for the biometric component of multifactor authentication. As shown on the Spring 2021 Unified Agenda,[126] rulemaking to address this mandate is currently in progress. After reviewing comments on the August 2020 RFI and CY 2021 PFS proposed rule and talking with industry stakeholders, we recognize that commenters believe that an update in the DOJ requirements should allow prescribers to start conducting EPCS with greater ease.

The comments also stated that prescribers have felt strained by the COVID–19 pandemic. Prescribers reported feeling financially strained, worried about their own health and the health of their employees, and concerned about having to make rapid changes during a time when they are continuing to cope with the effects of the COVID–19 pandemic on their practices, and their patients. Despite the strain that has been experienced by prescribers, we have noted an increase in EPCS during this PHE. In CY 2021, EPCS increased to 70 percent of all prescription drug events (PDEs) for controlled substances as compared to 38 percent in CY 2019.[127] We believe that social distancing is likely to be at least partly responsible for the increase in EPCS during this PHE for COVID–19. With the use of electronic prescribing, one potential prescriber-patient interaction in which COVID–19 could be transmitted is eliminated, and any necessary prescriptions can be electronically transmitted to the pharmacy without the prescriber and patient having to see each other in-person and risk transmitting COVID–19. Some insurers, including Part D plans, have been permitting medication refills, including for controlled substances, earlier than usual or for a more extended period of time than is allowed. Pharmacies that were not doing so before the pandemic have been delivering medications, or delivering them at no charge, and communities and individuals have worked together to design ways for vulnerable persons to continue to receive access to prescribed medications in tandem with government and private sector flexibilities during the PHE. We believe that these additional flexibilities may have encouraged prescribers to more broadly use EPCS, since it prevented them from having their prescription transmissions automatically denied. The reason for this is that EPCS transaction sets can pull certain pieces of required information for use in their transactions, which prevent the transactions from hitting system edits that would have previously prevented these practices.

[126] *https://www.reginfo.gov/public/do/eAgendaMain.*

[127] Based on Prescription Drug Event data processed through April 6, 2021.

4. Proposed Timeframe for EPCS Adoption

Section 2003 of the SUPPORT Act mandates that EPCS for Part D controlled substances begin on January 1, 2021. Due to this statutory mandate coupled with the aforementioned advantages provided by EPCS, we encourage all prescribers to adopt EPCS as soon as is feasible for them. However, as stated in our CY 2021 PFS final rule, we recognize that although EPCS is ultimately more efficient, implementing EPCS takes additional time and resources. It is for this reason that, in our CY 2021 PFS final rule, we finalized a policy stating that CMS would not take compliance actions before January 1, 2022.

In crafting this policy, we also examined responses from commenters encouraging earlier adoption of EPCS, due to its benefits for social distancing, improved patient safety and workflow efficiencies, fraud deterrence, adherence management, and reduced burdens. We agreed with commenters that EPCS has many benefits, which is why we specified an effective date of January 1, 2021 in our regulations, even though we declined to take compliance actions until January 1, 2022.

Since finalizing the CY 2021 PFS final rule, we have received additional prescriber feedback indicating concern with having to implement EPCS rapidly. We have also learned more about the degree to which prescribers have been adversely affected by the COVID–19 pandemic, and that the PHE and the widespread effects of the pandemic may last longer than we had anticipated last year. We want to ensure that our actions do not have unintended consequences, such as the abrupt discontinuation of prescribers' ability to prescribe controlled substances to vulnerable populations, including Part D beneficiaries who need pain treatment or who have SUDs. In addition, once DOJ has had the opportunity to implement updates to EPCS requirements, such updates will allow prescribers to start conducting EPCS more rapidly and easily. It is for these reasons that we are proposing to revise § 423.160(a)(5) to change the EPCS compliance date from January 1, 2022 to January 1, 2023. We welcome comments on this proposal, including whether commenters believe that we should maintain the January 1, 2022 compliance date, given the benefits of EPCS, and the feasibility for prescribers to adopt EPCS for Part D prescriptions by January 1, 2023.

We propose to extend the compliance deadline for Part D controlled substance prescriptions written for beneficiaries in long-term care (LTC) facilities, excluding beneficiaries who are residents of nursing facilities and whose care is provided under Part A of the benefit, from January 1, 2022 to January 1, 2025. The intent of this extension is to strike a balance between being responsive to stakeholder concerns surrounding the increased implementation barriers faced by LTC facilities, while at the same time helping ensure that these facilities eventually implement EPCS, due to its aforementioned benefits.

After considering the comments in response to our August 2020 RFI and CY 2021 PFS proposed rule, in addition to our conversations with stakeholders, we believe that LTC facilities face additional barriers to EPCS adoption that most prescribers do not face. In addition to the current challenge of having to manage care for vulnerable residents during the current COVID–19 pandemic, prescribers who work in LTC facilities or who provide care to residents in LTC facilities face technological barriers that other prescribers do not face. One such barrier is that the NCPDP SCRIPT 2017071 standard lacks appropriate guidance for LTC facilities. We understand that this is because early versions of the NCPDP SCRIPT Standard, such as NCPDP SCRIPT Standard versions 5.0 and 8.1, did not support the workflows in the LTC setting that require prescribers to issue a prescription for a patient to a non-prescriber (such as a nursing facility) that in turn forwards the prescription to a dispenser (LTC pharmacy). We nevertheless adopted the NCPDP SCRIPT 2017071 standard in the CY 2021 PFS final rule [85 FR 84807] because it is the most commonly used standard for Part D e-prescribing, and we sought to minimize disruption and provider burden when implementing this statutory mandate. However, we understand that NCPDP is in the process of creating specific guidance for LTC facilities within the SCRIPT 2017071 standard, which would allow willing partners to enable three-way communication between the prescriber, LTC facility and pharmacy to bridge any outstanding gaps that impede adoption of the NCPDP SCRIPT 2017071 standard in the LTC setting. We understand that NCPDP may be able to adopt these changes and integrate them into the LTC workflow by January 1, 2023.

We also understand that some LTC settings/services in rural communities do not have sufficient capabilities to support the NCPDP SCRIPT 2017071 standard. This concern is exacerbated by the fact that based on stakeholder feedback and information in several reports,[128] we believe LTC settings often include practitioners and staff serving large numbers of residents across multiple nursing homes. This unique set of circumstances means that some practitioners who primarily practice in suburban or urban areas may have to travel to see residents in rural facilities where there is limited broadband, making EPCS transmission set-ups difficult across LTC facilities. However, we believe that as broadband access increases and the impact of the pandemic decreases, LTCs should be able to more easily conduct EPCS.

As a result, we propose to revise § 423.160(a)(5) to clarify that compliance actions for prescriptions written for beneficiaries in an LTC facility will not begin until January 1, 2025. We do not propose a specific LTC waiver or exception to the EPCS requirement, and we do not anticipate extending the compliance deadline beyond January 1, 2025. We solicit comments on the benefits, burdens, and challenges of this approach.

5. Proposed Compliance Threshold

The EPCS requirement applies to all controlled substance prescriptions for Part D drugs under a Part D plan, unless an exception to the requirement applies. In order to implement this mandate effectively, however, we seek to implement it in a manner that balances the mandate with helping ensure that prescribers are not overly burdened, and are able to issue prescriptions for their patients during the rare occurrences when EPCS is not feasible, such as:

- When it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition,
- When the NCPDP standard does not support transmitting the prescription,
- When the prescriber is unable to meet DEA requirements for identity proofing for reasons beyond their control;
- Where EPCS is not available due to temporary technological failure.

Based on our review of PDE data, the NCPDP standard, and our conversations with Part D stakeholders, we believe that there are very few scenarios under which a prescription could not be transmitted using the NCPDP standard.

[128] Waters, Rob. The Big Idea Behind a New Model of Small Nursing Homes. Health Affairs. 2021 Mar; 378 – 383; Levy et al. Physician Practices in Nursing Homes: Final Report. Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2006 Apr; 10 – 22.

We note that the section 1860D–4(e)(7)(B)(vi) of the Act provides that the Secretary may grant an exception for a prescription issued for a drug for which the FDA requires a prescription to contain elements that cannot be included in electronic prescribing. However, after reviewing the NCPDP standard implementation guide, we do not believe that there are any such prescriptions under the current standard. The statute gives as an example a drug with risk evaluation and mitigation strategies that include elements to assure safe use. Based on our review of the current NCPDP standard, all opioids have risk evaluation and mitigation strategies and as a result, would fall into the exception if there were one, which would frustrate the purpose of this statute.[129] As a result, we decline to propose to adopt this suggested exception. However, we seek comment on this decision.

We do believe that other reasons could make EPCS not feasible for prescribers who currently conduct EPCS, such as the aforementioned cases of temporary technological failures or cases where it would be impractical for the patient to obtain medication(s) prescribed by electronic prescription in a timely manner and such delay would adversely impact the patient's medical condition. However, we are not proposing a specific exception for these cases, since based on our stakeholder feedback and review of PDE data, we believe that EPCS is not feasible in no more than an estimated 30 percent of instances due to circumstances such as the ones described previously. We believe that Part D prescribers should be able to conduct EPCS on 70 percent of their Part D controlled-substance prescriptions without being overly burdened or burdening patients. Under section 1860D–4(e)(7)(D) of the Act, we have authority to specify appropriate penalties for non-compliance with the EPCS requirement. It follows, then, that we similarly have the authority to specify a threshold for when we would penalize non-compliance. For this reason, we propose that in order for prescribers to be considered compliant with the EPCS mandate, they must prescribe at least 70 percent of their Part D controlled substance prescriptions electronically.

Specifically, we are proposing to revise § 423.160(a)(5) to specify that 70 percent of all prescribing under Part D for Schedule II, III, IV, and V controlled substances be done electronically per calendar year, excluding from that calculation any prescriptions issued while a prescriber falls within an exception or a waiver. We would conduct this calculation by examining PDE data at the end of the calendar year and dividing the number of Part D controlled substances that the prescriber e-prescribed by the total number of Part D controlled substance prescriptions that the prescriber prescribed. We seek comment on this method and the proposal to make 70 percent the compliance threshold for adherence to the EPCS mandate, and what circumstances would make EPCS not feasible.

6. Proposed Classes of Exceptions

a. Prescriptions Issued When the Prescriber and Dispensing Pharmacy Are Same Entity

Section 2003 of the SUPPORT Act requires that we specify circumstances by which we may waive the EPCS requirement, and the statute lists several possible circumstances to consider. We listed and sought comment on these circumstances in the August 2020 RFI. The first of these circumstances, which is listed at section 1860D–4(e)(7)(B)(i) of the Act, is when the practitioner issuing the prescription and dispensing pharmacy are the same entity.

All August 2020 RFI commenters who commented on this exception supported it, stating that such an exception would promote patient safety, workflow efficiency, and health IT performance. Several commenters noted that requiring EPCS in this circumstance may create an unwarranted artificial workflow structure. We believe that this may be because the EPCS transactions conducted within an organization are commonly handled by a single database that exists within the organization, and should we not grant this exemption, these entities would be required to reconfigure their own processes, rather than leverage their own integrated databases. Were we to implement a requirement to use the NCPDP SCRIPT 2017071 standard within this closed system, this requirement could increase costs and the rate of performance errors, such as data corruption and patient matching errors, which we understand often happens when an entity is forced to split a unified database into a transaction system that relays information to and from the same entity. We seek comment on this assumption.

As stated in our current regulation at § 423.160(a)(3)(iii), we currently allow Part D plans to use either HL7 messages or the NCPDP SCRIPT standard to transmit prescriptions or prescription-related information internally when the sender and the beneficiary are part of the same legal entity. This allowance stands in contrast to our overarching requirement at § 423.160(a)(1) and (3), for prescribers to use the NCPDP SCRIPT standard for most external transactions. We believe that allowing Part D plans to continue to have more discretion over their internal transactions is consistent with our current policy. Therefore, we propose to adopt at § 423.160(a)(5)(i) the EPCS exception listed in section 1860D–4(e)(7)(B)(i) of the Act, for prescriptions issued where the prescriber and dispensing pharmacy are the same entity. We seek comment on this proposal.

b. Cases Where Prescribers Issue Only a Small Number of Part D Prescriptions

As we develop regulations to implement section 2003 of the SUPPORT Act, we seek to help ensure that Part D prescribers, including small prescribers (which CMS will define in subsequent rulemaking), are not overly burdened by our regulation. Based on the comments received from the August 2020 RFI and the stakeholder feedback that we received about EPCS in general, we believe it is appropriate to specify circumstances for a waiver of the EPCS requirement in cases where a prescriber issues a very low volume of controlled substance prescriptions for Part D drugs. For prescribers of very few Part D controlled substance prescriptions, the cost of installing EPCS equipment and software may be unduly burdensome relative to its benefit in terms of improving the security of prescriptions for controlled substances. As noted above, we do not want to disincentivize prescribers from prescribing controlled substances to Part D beneficiaries altogether, especially those who have few beneficiaries who need them.

After reviewing the current PDE data and the costs associated with implementing EPCS, we propose to exempt prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year. Based on our stakeholder feedback, we understand that EHR companies provide the initial electronic prescribing set-up free of charge, provided the prescribers transmit a minimum number of transactions per year. We estimate that this amount is, on average, 100 Part D controlled substance transactions. In order to do EPCS, prescribers would have to have the capability to e-prescribe more broadly. It is for this reason that we weighed the cost of e-prescribing set-up in general, even though we do not intend to include non-part D prescriptions of controlled or

[129] National Council for Prescription Drug Programs, ''Implementation Guide'' January 2020.

non-controlled substances in our calculation of whether or not prescribers meet the threshold of 100 Part D controlled substance prescriptions per year. Since, based on our conversations with stakeholders, the cost of EPCS transactions is less than the cost of transmitting certain transactions manually, we believe that the initial investment to install EPCS equipment and software is likely justified once prescribers transmit more than 100 Part D controlled substance prescriptions per year. We seek comment on this assumption. Although we understand that prescribers will be required to purchase third party applications with additional identity and security measures so that EHRs meet DEA requirements, we have not included this cost in our calculation, due to the wide variability of these costs for which there is a dearth of information. We seek stakeholder feedback on the costs of these third-party applications.

We believe that requiring prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year to purchase and construct EPCS hardware and software may be financially burdensome for these prescribers compared to the benefits of EPCS, since any reduced costs from EPCS transactions may not be enough to justify the initial start-up costs for purchasing and installation of EPCS hardware and software. We also believe that the cost of any future CMS compliance actions may be too great to justify when 100 or fewer Part D controlled substance prescriptions per year are at issue. Although we considered using a lower threshold (such as 50) or a higher threshold (such as 200), we believe that 100 Part D controlled substance prescriptions per year strikes the right balance between helping ensure that we implement section 2003 of the SUPPORT Act's EPCS mandate and that prescribers can use resources appropriately.

In order to implement this exception using the data that we have available, we are proposing that this exception be given to individual prescribers, regardless of the size of the group practice that they belong to. We also believe that this exception would protect these small prescribers, should they change their place of employment or if their place of employment does not offer support for implementing EPCS. We seek comment on this proposal.

Based on our examination of PDE data and conversations with stakeholders, we believe that prescribers working under most research protocols would fall under the proposed exception for small prescribers. However, we seek comment on this assumption. Although we have not proposed to adopt the suggested exception listed in section 1860D–4(e)(7)(B)(v) of the Act, which describes an exemption for prescribers working under a research protocol, we believe that in most cases prescribers who would fall within this category would be included in the exception for small prescribers or in the exception for cases where the prescriber and dispenser are the same entity. We decline to propose to specifically create an exception for prescribers working under a research protocol in the regulations, since we believe that so few prescribers would fall outside of these other exceptions. We believe an exception for prescribers working under a research protocol who do not otherwise meet these exceptions is unnecessary because we believe that EHR companies will set up the appropriate EHR equipment, provided around 100 Part D controlled substance prescriptions are transmitted per year. We propose to implement this proposal by examining PDE claims as of December 31 of the prior year to determine which prescribers fall within this exception. Prescribers can ascertain whether they meet this exception by looking at how many prescriptions for Part D controlled substances they conducted the prior year or by contacting the CMS contractor responsible for administering the compliance portion of this mandate. CMS and its contractor will be using PDE data from the prior year to determine whether the prescriber qualifies for the exception based on the number of Part D controlled substance claims the prescriber had issued the previous year. CMS will use the previous year's data to determine whether or not the prescriber falls under this exception for the year-in-question. We do not see a compelling reason to exempt prescribers conducting a research protocol on that basis alone.

Based on our conversations with Prescription Drug Plans (PDPs), MA–PD plans, and other organizations with which prescribers are affiliated, we are aware that some are willing to donate the technology and services necessary for prescribers to adopt EPCS. Based on those conversations, we believe that they are more willing to donate these technology and services to prescribers who are working under a research protocol, than to prescribers not working under such a protocol. However, we seek comment on such an assumption. We believe that, to the extent this is an accurate assumption, such donations further decrease the burden for prescribers working under a research protocol. It is for these additional reasons that we have declined to propose an exception for those working under a research protocol. We seek comment on this decision.

We propose to amend § 423.160(a)(5) by adding § 423.160(a)(5)(ii), which creates an exception for prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data as of December 31st of the preceding year, so that these prescribers will not be required to meet the EPCS requirement. We seek comment on this proposal, including regarding the maximum number of Part D controlled substance prescriptions a prescriber can issue to be still considered a small prescriber and, so, to fall within this exception.

c. Cases of Recognized Emergencies and Extraordinary Circumstances

Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, lists an exception for consideration by the Secretary for cases of exceptional circumstance demonstrated by the prescriber. As stated in our proposal regarding the EPCS compliance threshold, we seek to help ensure that prescribers are able to issue prescriptions for their patients during the rare occurrences when EPCS is not feasible. We believe that the exception listed in the statute, which includes economic hardship, technological limitations that are not reasonably within the control of the prescriber, and other exceptional circumstances, includes prescribers who are overwhelmed due to having to treat patients during a pandemic or a natural disaster such as a hurricane, flood, or earthquake. It is our goal not to penalize prescribers for such circumstances, and we do not want to unduly increase their burden during difficult situations that impact them, and their patients. We seek comment on what other extraordinary circumstances may prevent prescribers from being able to conduct EPCS.

In order to help ensure that these extraordinary circumstances are accounted for, we are proposing two exceptions to the EPCS requirement. The first exception, at proposed § 423.160(a)(5)(iii), is for prescribers who are prescribing during a recognized emergency, such as a natural disaster, a pandemic, or a similar situation where there is an environmental hazard. We want to help ensure that the EPCS mandate does not interfere with necessary care for patients, especially during natural disasters or pandemics.

As a result, we are proposing to exempt prescribers who are issuing prescriptions in areas that are affected by such circumstances. To qualify for this exception, this circumstance would have to arise from an emergency or disaster declared by a federal, state, or local government entity. We would determine whether a prescriber qualifies for this exception based on whether the prescriber's NCPDP database address is located in the geographic area of an emergency or disaster declared by a federal, state or local government entity.

The second exception, at proposed § 423.160(a)(5)(iv), is for prescribers who request and receive from CMS a waiver, which CMS would grant to prescribers who are facing extraordinary circumstances that prevent them from electronically prescribing a controlled substance to a Part D beneficiary, but who are not in an emergency or disaster area. We define ''extraordinary circumstance'' to mean a situation, other than an emergency or disaster, outside of the control of a prescriber that prevents the prescriber from electronically prescribing a controlled substance to a Part D beneficiary. An example of such a circumstance would be if a prescriber was in a service area that lacks broadband access or EPCS providers refuse to install systems for the prescriber. The prescriber would have to be able to submit evidence of such an extraordinary circumstance to CMS.

For purposes of the exception at proposed § 423.160(a)(5)(iii), prior to imposing any compliance actions on a prescriber, we would ascertain whether there is an emergency or disaster declared by a federal, state, or local government entity for the geographic area associated with the prescriber's address in the NCPDP database.

For purposes of the proposed exception at proposed § 423.160(a)(5)(iv), we are proposing that prescribers will be excepted from the EPCS requirements if they request and receive a waiver from CMS. We intend that prescribers will be able to submit a request for a waiver to inform CMS of any extraordinary circumstances that they may be facing and that would prevent the prescriber from conducting EPCS. This waiver could be for any circumstance outside of the prescriber's control and does not require an official declaration by a state or local government. To meet the standard for a waiver, prescribers must provide documentation showing the existence of a circumstance beyond their control and that such a circumstance prevents them from conducting EPCS. Section 1860D–4(e)(7)(B)(iii) of the Act, as added by section 2003 of the SUPPORT Act, refers to a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, which suggests a timeframe not to exceed one year, but to be determined by the Secretary.

We have proposed the first part of the waiver process below and will include more information about it in subsequent rulemaking. We welcome stakeholder comments on a potential waiver process.

To implement this proposal, we propose to amend § 423.160(a)(5) by adding paragraphs (a)(5)(iii) and (iv). Section 423.160(a)(5)(iii) would specify an exception for prescribers in the geographic service area of an emergency or disaster declared by a federal, state or local government entity. Section 423.160(a)(5)(iv) would clarify that prescribers would be exempt from the EPCS requirements if they have received a CMS-approved waiver certifying that the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. In order to receive a CMS-approved waiver, the prescriber would have to submit an attestation using a form, which would be made available on a CMS-supported website, so that prescribers will be able to request a waiver via an online portal.

The following minimum set of information would be required on the attestation:

- Prescriber's first and last name;
- Prescriber's NPI;
- Prescriber's taxpayer identification number (TIN) or TIN associated with his or medical practice, when applicable;
- Prescriber's contact information, including name, email address, telephone number, and mailing address; and
- A description of the extraordinary circumstance necessitating a waiver and how it affects the prescriber.

Following receipt of the attestation, we will: (1) Provide a written acknowledgement of receipt of the request using the contact information submitted via the portal and (2) provide a decision formally granting the attestation using the contact information submitted via the portal. Under the proposed policy, the prescriber would submit their attestation about the circumstance and receive a waiver based on such an attestation. We welcome comments on the different aspects of this proposal.

d. Individuals in Hospice and Nursing Facilities

Section 2003 of the SUPPORT Act, in adding section 1860D–4(e)(7)(B)(vii) to the Act, tasked the Secretary to consider whether prescriptions for individuals under the Part D benefit for an individual enrolled in the Medicare Part A Hospice benefit should be exempt from the EPCS requirement. After considering this issue, we believe that an exception for a prescription made for an individual enrolled in hospice would be inappropriate for several reasons. First, when electing hospice, patients have chosen to move from a curative model of care to a holistic palliative model of care. Regulations at 42 CFR 418.202(f) stipulate that the Medicare hospice benefit covers only drugs and biologicals used primarily for the relief of pain and symptom control for the terminal illness and related conditions. Under section 1860D–2(e)(2)(B) of the Act, a drug is excluded from Part D coverage if payment for such drug, as prescribed and dispensed for the beneficiary, is available under Medicare Part A or Part B. Thus, in cases where, with respect to a beneficiary, the hospice benefit covers a drug or biological used primarily for the relief of pain or symptom control for the terminal illness or related conditions, such drug is excluded from Part D under section 1860D–2(e)(2)(B) of the Act. The HHS OIG worked with CMS and the National Hospice and Palliative Care Organization (NHPCO) to identify four common categories of prescription drugs that are typically used to treat symptoms often experienced during the end of life, regardless of an individual's terminal diagnosis.[130] The OIG has found that these categories of drugs should generally be paid under the hospice benefit.[131] Thus, there may be very few instances in which a controlled substance prescribed for a Part D enrollee who has elected hospice could be covered under Part D. We believe an exception that would apply only in these rare instances could be confusing and burdensome for prescribers who furnish care to some Part D beneficiaries who are enrolled in hospice and for some who are not because to qualify for the exception they would have to determine when a particular enrollee has elected hospice. Further, a beneficiary is free to elect the hospice benefit and cancel that election as they choose, which would make it difficult for a prescriber to be sure at any point in time whether a beneficiary is, or is not, currently enrolled in hospice and therefore whether a paper prescription is permitted. We note that the EPCS

[130] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/Downloads/2014-PartD-Hospice-Guidance-Revised-Memo.pdf.*

[131] *https://oig.hhs.gov/oei/reports/oei-02-16-00570.pdf.*

requirement would not apply to any prescriptions for Part A or Part B controlled substances in any event.

Further, were CMS to provide an exception for prescriptions for Part D-covered controlled substances for hospice enrollees, it would pose an operational challenge to accurately match prescription data records with hospice enrollment data where the patient's hospice status can be fluid. It would be operationally challenging to ensure that paper prescriptions were only issued for beneficiaries enrolled in hospice (which would be permitted), and not for patients not enrolled in hospice (where EPCS would be required). We believe the cost of this potentially confusing and laborious analysis for the small number of prescriptions dispensed for beneficiaries enrolled in hospice but covered under Part D exceeds the benefit creating the exception would provide to prescribers.

Therefore, we decline to propose an exemption for prescribers issuing prescriptions for individuals enrolled in hospice. However, we seek comment on this decision.

Section 1860D–4(e)(7)(B)(viii) of the Act suggests an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits. We sought stakeholder feedback on this exemption in our August 2020 RFI and discussed it with our federal partners at the DEA, and have been informed that there are situations where nursing facilities experience or are at risk of drug diversion. This stakeholder feedback did not inform us of any compelling reasons to include an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits. We have also seen the severe impact that the COVID–19 pandemic has had on nursing facility residents, who are at high risk for infection, serious illness, and death from COVID–19, as well as other infectious diseases including clostridium difficile and the seasonal flu. It is for these reasons that we decline to propose an exemption for prescribers issuing prescriptions for individuals who are residents of a nursing facility and eligible for Medicare and Medicaid benefits. However, we seek comment on this issue.

7. Fraud and Abuse Laws

We are aware that Prescription Drug Plans (PDPs), MA–PD plans, or other organizations with which prescribers are affiliated may wish to assist prescribers with satisfying the mandate for electronic prescribing of controlled substances for a covered Part D drug by providing technology and services necessary to effectuate the electronic prescribing of such drugs. Such assistance may implicate the payment and fraud and abuse laws that govern the financial relationships in the health care industry. Specifically, the donation of free or below-fair market value electronic prescribing technology or services to a practitioner (or any other person) may implicate the physician self-referral law and the federal anti-kickback statute. However, there is an exception to the physician self-referral law's prohibition and a corresponding safe harbor under the federal anti-kickback statute that would permit certain donations in the form of items or services (not including cash or cash equivalents) necessary and used solely to receive and transmit electronic prescription information if all requirements of the applicable exception or safe harbor are satisfied. In addition, other exceptions to the physician self-referral law and safe harbors under the federal anti-kickback statute may apply.

Section III.P.1. of this proposed rule provides a general discussion of the application of, prohibitions of, and exceptions to the physician self-referral law. For information specific to the exception for donations of electronic prescribing items and services, we refer readers to our August 8, 2006 final rule entitled ''Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements'' (71 FR 45140) and found at *https://www.govinfo.gov/content/pkg/FR-2006-08-08/pdf/06-6667.pdf,* and the regulations interpreting the physician self-referral law, including additional exceptions to its prohibitions, which are found in 42 CFR part 411, subpart J. Information regarding the federal anti-kickback statute and its applicable safe harbors can be found at *www.oig.hhs.gov.*

8. Penalties

Section 1860D–4(e)(7)(D) of the Act gives the Secretary the authority to enforce and specify appropriate penalties for non-compliance with the EPCS requirement. We sought stakeholder feedback on whether CMS should impose penalties and if so, what those penalties should be. We have also examined state EPCS requirements and their accompanying penalties. However, because these requirements have only been recently implemented and most states do not have penalties for failing to adopt EPCS, we have not been able to evaluate what type of penalties have been effective for state mandates.

In implementing the EPCS requirement, we seek to help ensure that we do not place too much of a burden on prescribers, as we do not want this requirement to have an unintended consequence of incentivizing prescribers to stop prescribing controlled substances to Part D beneficiaries, as appropriate, should they not have EPCS set-up. We also need sufficient time to gather more stakeholder feedback on the most effective and most appropriate type of penalties.

Therefore, we propose that with respect to compliance from January 1, 2023 through December 31, 2023, CMS compliance actions will consist of sending letters to prescribers that we believe are violating the EPCS requirement during that period of time. These letters will consist of a notification to prescribers that they are violating the EPCS requirement, information about how they can come into compliance, the benefits of EPCS, an information solicitation as to why they are not conducting EPCS, and a link to the CMS portal to request a waiver. We will re-evaluate whether further compliance actions will be necessary and what those compliance actions will be in future rulemaking. We seek comment on this proposal, including what type of compliance action may be appropriate after the initial period described above, including whether any penalties should be phased in over time.

R. Open Payments

1. Background

a. Open Payments Policies

The Open Payments program is a statutorily-mandated program that promotes transparency by providing information to the public about the financial relationships between the pharmaceutical and medical device industry, and certain types of health care providers. Section 1128G of the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as ''applicable manufacturers''), as well as applicable group purchasing organizations (GPOs), to annually submit information for the preceding calendar year about certain payments or other transfers of value made to ''covered recipients,'' currently defined as physicians, teaching hospitals, physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), certified registered

nurse anesthetists (CRNAs) & anesthesiologist assistants (AAs), and certified nurse-midwives (CNMs).

Payments or other transfers of value that must be reported include such things as research-related payments, honoraria, gifts, travel expenses, meals, grants, and other compensation. The type of information required to be reported includes, but is not limited to, the date and amount of the payment or other transfer of value, identifying information about the covered recipient, and details about products associated with the transaction. When a payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological or medical supply, the name of that covered drug, device, biological or medical supply also must be reported. The estimated burden of these reporting requirements, as outlined under OMB control number 0938–1237, is approximately 1.9 million hours over the course of 1 year.

Section 1128G of the Act establishes certain minimum dollar thresholds for required reporting, with two bases for reporting: Individual and aggregate payments or transfers of value. To determine if multiple small individual payments or other transfers of value made to a covered recipient exceed the aggregate threshold and therefore must be reported, applicable manufacturers and applicable GPOs must aggregate all individual payments made across all payment categories within a given reporting year. The statutory threshold established in 2013 was $10 for individual payments and $100 for aggregated payments, and this amount has increased with the consumer price index each year. For CY 2021, the annual reporting thresholds for individual payments or other transfers of value is $11.04 and the aggregate amount is $110.40.

The Open Payments program yields information to the general public about providers, as well as information that researchers may use to look into potential correlations between financial relationships and provider behaviors. Between August 2013 and the June 2020 publication, more than 76 million records have been disclosed under the Open Payments program, enabling significant transparency into applicable exchanges of value. We have been committed to stakeholder engagement in an effort to limit the burden in the Open Payments program reporting processes and improve clarity for the public. Additional background about the program and guidance, including frequently asked questions, regarding how the program works and what type of information is required to be reported is available at *www.cms.gov/OpenPayments.*

In the February 8, 2013 **Federal Register** (78 FR 9458), we published regulations implementing section 1128G of the Act and establishing the Open Payments program. Section 1128G of the Act requires applicable manufacturers and applicable GPOs to submit information annually about certain payments or other transfers of value made to covered recipients during the course of the preceding calendar year. Additionally, section 1128G of the Act defines covered drugs, devices, biologicals, or medical supplies as those covered under Medicare, a state plan under Medicaid, or the Children's Health Insurance Program (CHIP) (or a waiver of either such state plan), and requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or physicians' immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Under section 1128G(e)(10)(A) of the Act, the term ''payment or other transfer of value'' refers to a transfer of anything of value, though some exclusions apply.

In the CY 2015 PFS final rule with comment period (79 FR 67548), we amended the regulations by standardizing reporting in the Open Payments program. Specifically, we: (1) Deleted the definition of ''covered device''; (2) removed the special rules for payments or other transfers of value related to continuing education programs; (3) clarified the marketed name reporting requirements for devices and medical supplies; and (4) required stock, stock options, and any other ownership interests to be reported as distinct forms of payment.

In the CY 2017 PFS proposed rule (81 FR 46395), we solicited information from the public on a wide variety of topics regarding the Open Payments program. Since the implementation of the program and changes made in the CY 2015 PFS final rule with comment period, various commenters have provided us feedback. Consequently, we identified areas in the rule that might benefit from revision and solicited public comments to inform future rulemaking. We sought comment on whether the payment categories listed at 42 CFR 403.904(e)(2) are adequately inclusive to facilitate reporting of all payments or transfers of value, as well as ways to streamline or make the reporting process more efficient while facilitating our role in oversight, compliance, and enforcement, along with posing other program-specific questions. A summary of the comments we received was published in the CY 2017 PFS final rule (81 FR 80428 through 80429).

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271) was signed into law. Section 6111 of the SUPPORT Act amended the definition of ''covered recipient'' under section 1128G(e)(6) of the Act with respect to information required to be submitted on or after January 1, 2022, to include PAs, NPs, CNSs, CRNAs, and CNMs, in addition to the previously listed covered recipients of physicians and teaching hospitals. In the CY 2020 PFS final rule, we codified the Open Payments provisions of the SUPPORT Act and addressed public comments received from the CY 2017 PFS proposed rule by simplifying the process for reporting data by adjusting the Nature of Payment categories, and standardized data on reported covered drugs, devices, biologicals, or medical supplies.

In this rule, we propose to clarify existing Open Payments requirements, as well as add provisions that program stakeholders have requested and we agree would improve the quality of the data. We propose the following revisions effective for data collection beginning in CY 2023 and reporting in CY 2024: (1) Adding a mandatory payment context field for records to teaching hospitals; (2) adding the option to recertify annually even when no records are being reported; (3) disallowing record deletions without a substantiated reason; (4) updating the definition of ownership and investment interest; (5) adding a definition for a physician-owned distributorship as a subset of applicable manufacturers and group purchasing organizations, for the purposes of Open Payments program reporting only, which definition would not apply for purposes of any other laws or regulations, including, but not limited to, section 1128B of the Act (the federal Anti-Kickback statute), the regulations at 42 CFR 1001.952, and materials interpreting the anti-kickback statute, such as Special Fraud Alerts; and section 1877 of the Act and the regulations at 42 CFR part 411, subpart J (collectively, the physician self-referral law); (6) requiring reporting entities to disclose relationships they have with other companies for the purposes of transparent reporting; (7) disallowing publications delays for general payment records; (8) clarifying the exception for short-term loans applies for 90 total days in a calendar year, regardless of

whether the 90 days were consecutive; and (9) removing the option to submit and attest to general payment records with an ''Ownership'' Nature of Payment category. We believe these changes will increase the usability of the data, address concerns we have heard from stakeholders, and give reporting entities sufficient time to prepare for changes to their data collection and reporting procedures.

b. Legal Authority

Four legal authorities from the statute ground our provisions:

- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1861 of the Act, which defines providers and suppliers.
- Section 1128G of the Act, as amended by section 6111 of the SUPPORT Act, which requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare or a state plan under Medicaid or CHIP to report annually to the Secretary certain payments or other transfers of value to physicians and teaching hospitals, and to PAs, NPs, CNSs, CRNAs, and CNMs for information required to be submitted under section 1128G of the Act on or after January 1, 2022.

c. Provisions of the Proposed Regulations

(1) Payment Context Field for Teaching Hospitals

We have received feedback from teaching hospitals during informal interviews that Open Payments submissions do not contain sufficient information to identify reported payments or transfers of value in their own records. This means that teaching hospitals are unable to verify records during the review and dispute process and must dispute the record in order to obtain additional information, which yields additional and unnecessary work for both teaching hospitals and reporting entities.

To reduce the burden created by disputes for both reporting entities and teaching hospitals, we are proposing a mandatory context field for payments or transfers of value attributed to teaching hospitals, which would contain information to better identify the payment as deemed appropriate by the applicable manufacturer or GPO. Examples of data that the reporting entity may choose to include are: The check number or electronic wire number for the payment; related department of the hospital; or other pieces of relevant information.

(2) Optional Annual Recertification

Over the course of the program, we have received feedback from several companies that they would like the ability to attest that they do not have any reportable records for that year. At this time, any entity that does not have any reportable payments or transfers of value does not need to recertify in Open Payments, but also does not have a way to communicate to CMS that it believes it is still compliant even though it has not reported.

We propose to make it optional for a company that does not have reportable payments or transfers of value for the program year to recertify their registration in Open Payments and attest that it does not have any records to submit, which would give peace of mind to reporting entities which are correctly not reporting records. We believe this optional recertification for entities without reporting requirements would be low burden to reporting entities, but would be invaluable to ensuring the integrity of the data. We propose adding the following language to an option for entities that are recertifying without submitting records:

''1. I attest that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer equivalent authorized representative for the reporting applicable manufacturer or applicable group purchasing organization with the authority to attest to the information submitted in the Open Payments system.

2. I attest that, to the best of my knowledge, belief, and ability, my organization does not have any reportable payments or transfers of value or ownership and investment interest to report for the current program year.

3. If I become aware of any information that my entity is required to report, I will submit this information to CMS as required per 42 CFR 403.908(h)(1), which states that if an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.''

(3) Defining a Physician-Owned Distributorship

The preamble of the 2013 Open Payments final rule (78 FR 9458) discusses physician-owned distributorships (PODs), as a subset of group purchasing organizations (GPOs), but does not provide a specific definition for this type of entity. Reporting entities currently have the ability to self-identify as a POD when registering with Open Payments, but due to the lack of a definition of the term ''physician-owned distributorship'' or ''POD,'' this designation is not required. We believe that the disclosure of an entity's status as a POD is essential to the transparency that is central to the program, and will also help clear up confusion about whether PODs are required to report. Accordingly, we propose to include the definition of a POD as set out at § 403.902 as a subset of either an applicable manufacturer or applicable GPO.

We are also proposing to include language at § 403.908(c)(4) to require PODs to self-identify when registering or recertifying.

Furthermore, to better align the Open Payments program with the updated definition of ownership and investment interest at § 411.354(b)(3) (see 85 FR 77587), we are including the exceptions for titular ownership and employee stock ownership programs (ESOPs) that are qualified under IRS regulations for consistency in application.

In addition, we emphasize that:

- The proposed definition of a physician-owned distributorship does not apply for purposes of any other laws or regulations, including, but not limited to, section 1877 of the Act, the regulations at 42 CFR part 411, subpart J, section 1128B of the Act, or the regulations at 42 CFR 1001.952.
- ''Ownership or investment interest'' is defined at § 403.902 of the Open Payments regulations and would not include publicly traded securities or mutual funds.
- To be considered a physician owner(s), the owner would have to hold at least one active professional license to practice as a physician issued by a U.S. state or territory.
- If a company with common ownership reports in a consolidated report with the POD, the reporting company would only be required to register as a POD if it meets the 5 percent ownership requirement when ownership of all entities in the report is calculated.
- The POD would be required to report ownership and investment interest as required by existing Open Payments requirements. Ownership or investment interest is defined at § 403.902 to include, but is not limited to: Stocks, stock option(s) (other than those received as compensation, until they are exercised); partnership shares, both limited and non-limited; limited liability company memberships; loans, bonds, or other financial instruments

that are secured with an entity's property or revenue or a portion of that property or revenue. This definition explicitly excepts titular ownership and ESOPs that are qualified under IRS regulations.

- The POD would be required to identify as a POD whether or not the physician has a controlling interest in the reporting entity (for example, a silent partner whose only role is to provide capital and is not involved in the company's operations would still meet requirements for reporting).
- Five percent interest would be calculated as 5 percent of the total dollar value in USD of all ownership in the POD as of December 31, or the latest date that the ownership was held, as of the calendar year proceeding the Program Year. For example, if reporting ownership in a POD for Program Year 2022, the ownership would be calculated as of December 31, 2022, or the latest date in the calendar year that the physician held the ownership or investment interest.
- Indirect ownership interest would also have to be reported as required by § 403.902. Indirect ownership is often the result of the use of holding companies and parent/subsidiary relationships.
- Any entity meeting this definition would be required to identify itself as a POD when submitting and attesting to its records. For example, if an applicable manufacturer meets the definition of a POD, it may not choose to identify itself simply as an ''Applicable Manufacturer'' but would have to choose its business type as ''Applicable Manufacturer—Physician Owned Distributorship.''
- We believe that this proposed definition should not increase industry burden because it is a subset of existing definitions, but should clarify confusion about PODs being outside of reporting requirements.

(4) Disallowing Record Deletion Without Reason

While we have not seen evidence of the following behavior, we believe that our existing regulations might allow entities to be compliant by reporting and attesting to records, then deleting those records so that they are never publicly available. We propose to prevent reporting followed by deletion by adding language at § 403.904(a)(3) that would state that an entity that has reported payments or transfers of value under the scope of this rule may not remove, delete, or alter the records in the Open Payments system unless it discovers an error in the information furnished, or the record is otherwise believed to meet existing exceptions for reporting that were previously unknown.

An example of a properly deleted record would be the deletion of ownership records that were reported for a publicly traded company, since publicly traded companies are not required to report ownership and investment interest. We would add a dialogue box in the system for reporting entities to provide a reason for record deletion. We note that deletions will continue to undergo additional scrutiny to ensure the integrity of the data.

(5) Disallow Publication Delays of General Payments

Delayed publication is permitted for Open Payments records based on concerns that the information provided in the record details may reveal proprietary information about a company's research activities. According to § 403.910, only payments that are made in connection with (1) Research or on development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply or (2) Clinical investigations regarding a new drug, device, biological, or medical supply'' are allowed to be delayed from publication. As of December 26, 2020, there were 20,930 general records with a value of $26.4M that were delayed from publication for at least one Program Year, and based on the information provided in the current format required for the submission of general records, we are unable to verify these records' connection with research or clinical investigations. Therefore, we propose to eliminate the ability to delay general payments from publication and only permit publication delay of research payments, whose formatting does require the appropriate information to be provided, the details of which are specified at § 403.904(f).

Reporting entities may hesitate to include records that are currently being delayed as general payments because they are associated with a research study, but not directly outlined in that research agreement. For example, a company may pay for an airline ticket for a physician to conduct research that is associated with a research agreement, but that travel was not explicitly outlined in that agreement. However, we do not believe that the current requirements for a research payment would exclude these types of payments from being reported as research payments, as long as they are made in connection with, and subject to, a research agreement.

(6) Short Term Loans

The Open Payments final rule makes a reporting exception for short term equipment loans. A short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

The Open Payments regulations also clarify that for a single product the total number of days for the loan should not exceed 90 days for the entire year, regardless of whether the 90 days were consecutive. We believe that this aligns with the intention to limit the loan period to 90 days and not allow a new loan to start at the end of the previous loan period, thus avoiding the reporting requirements. We propose to clarify this by stating that short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 cumulative days per calendar year or a quantity of 90 cumulative days of average daily use per calendar year, to permit evaluation of the device or medical supply by the covered recipient.

g. Remove General Ownership Records

We currently have two ways for an entity to report ownership: Entities may submit an ownership record or a general record with a Nature of Payment category of ''Ownership.'' We propose to remove the ''Ownership'' Nature of Payment category. The statute requires special rules for the reporting of ownership interest, including dollar amount invested and value of interest, which is not captured by the general payment with the Nature of Payment category of ''Ownership.'' Furthermore, this proposal would create a cleaner and more consistent data set.

(7) Updated Contact Information

When sending communications to entities, the Open Payments program often finds that their contact information is outdated, especially if the entity has not recertified recently. It is important for the integrity of the data that the program is able to contact the reporting entities in case of perceived irregularities or potential noncompliance. We propose to make it mandatory for a company that has had reportable payments or transfers of

value within the past 2 calendar years to keep its contact information current within the Open Payments system. For example, if an applicable manufacturer or group purchasing organization had reported records in Program Years 2018 and 2022, but did not have records for Program Years 2019, 2020, or 2021, it would be required to keep updated contact information in the system during Program Years 2019 and 2020. The applicable manufacturer or group purchasing organization would not have to update its contact information for Program Year 2021. In Program Year 2022, since it once again had reportable records, it would be required to recertify and update its contact information as usual. We propose to include this requirement at § 403.908(c)(3).

IV. Summary of the Quality Payment Program Proposed Provisions

A. CY 2022 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule sets forth changes to the Quality Payment Program starting January 1, 2022, except as otherwise noted for specific provisions. The 2022 MIPS performance period/2024 MIPS payment year of the Quality Payment Program continues to build on the first few years of implementation of the Quality Payment Program to focus more on our measurement efforts, refine how clinicians will be able to participate in a more meaningful way and encourage participation in Advanced Alternative Payment Models (APMs).

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is an incentive program that includes two participation tracks, the Merit-based Incentive Payment System (MIPS) and Advanced APMs. MIPS eligible clinicians are subject to a MIPS payment adjustment based on their performance in four performance categories: Cost, quality, improvement activities, and Promoting Interoperability. The weights of those four performance categories are specified in statute. For CY 2022, those weights are as follows: 30 percent for the quality performance category, 30 percent for the cost performance category, 15 percent for the improvement activities performance category, and 25 percent for the Promoting Interoperability performance category. If an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) status, they are excluded from the MIPS reporting requirements and payment adjustment. Those that are qualifying APM participants (QPs) for the year receive a 5 percent lump sum incentive payment during the corresponding payment year through CY 2024, or a differential payment update under the PFS for payment years beginning in 2026.

Participation in the Quality Payment Program rose in the third year. We saw 99.99 percent of eligible clinicians participate in MIPS in 2019 with 954,614 MIPS eligible clinicians receiving a payment adjustment, which exceeded our 2018 participation rates. In addition, 97.6 percent of eligible clinicians participating in MIPS received a positive payment adjustment for 2021 based on 2019 performance year results. Regarding performance in Advanced APMs, for the 2019 QP Performance Period, 195,564 eligible clinicians earned Qualifying APM Participant (QP) status while another 27,995 eligible clinicians earned partial QP status. [132] We note that due to the Public Health Emergency (PHE) for COVID–19, 65,237 (or about 6.83 percent of 954,614) MIPS eligible clinicians received reweighting for performance year 2019 of one or more MIPS performance categories due to our MIPS extreme and uncontrollable circumstances policy.

We plan to continue developing Quality Payment Program policies that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We are moving forward with MIPS Value Pathways (MVPs) as MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population. The MVPs would include the Promoting Interoperability performance category as a foundational element and incorporate population health claims-based measures, as feasible, along with relevant measures and activities for the quality, cost, and improvement activities performance categories. To provide clinicians and third party intermediaries with sufficient time to prepare for a shift to this new participation framework, in this rule, we are proposing to begin transitioning to MVPs in the 2023 MIPS performance year.

As we make long-term improvements, evolve MIPS policies, and plan to implement MVPs in the future, we remain committed to our program goals. We are aligning with broader CMS initiatives, such as the CMS Quality Measure Action Plan (*https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf*), to unify strategic efforts to adopt measures most critical to providing high quality care and accelerate strategic improvements for quality programs and measures. The vision for the CMS Quality Measure Action Plan is to use impactful quality measures to improve health outcomes and deliver value by empowering patients to make informed care decisions while reducing burden to clinicians. This plan supports CMS's work to identify activities for transformation of quality measurement and value-based programs and recognizes the need to modernize the current quality ecosystem of measurement and programs. Additionally, it will encourage further reductions to the burden of quality measure reporting and address the current lack of alignment. These efforts will also support identifying activities that are driving better patient outcomes at lower costs. The planned implementation of MVPs aligns with many of the objectives and goals the CMS Quality Measure Action Plan will strive to achieve.

Through the proposals we describe below, we intend to transform and simplify the MIPS program through MVPs, promote the use of connected measures and activities, reward clinicians for providing high value care, and help all clinicians improve care and engage patients. We also intend to gather information from stakeholders to help guide efforts to advance health equity throughout CMS quality programs.

b. Summary of Major Provisions

(1) Major MIPS Provisions

The MIPS program aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. Within MIPS we intend to pay for health care services in a way that drives value by linking performance on cost, quality, and the patient's experience of care.

We have heard from clinicians that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality

[132] QPP Participation in 2019: Results at-a-Glance released 10/27/2020 at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1190/QPP%202019%20Participation%20Results%20Infographic.pdf.*

measures that are meaningful to their practices and have a direct benefit to patients. We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due in part to clinician quality measure selection bias. These aspects detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. MVPs are intended to lead to a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians. We noted that the MVP framework would connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. We intend to focus the future of MIPS on MVP development and implementation.

Additionally, we have heard from patients, clinicians, and other stakeholders that they would like more comprehensive and granular reporting from the MIPS program. To that end, we are proposing to establish voluntary subgroup reporting to help provide patients and clinicians information that is clinically meaningful at a more granular level.

We are additionally issuing a request for information (RFI) to address the Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs please refer to section IV.A.1.c. of this rule for more information. We are also issuing an RFI to address Closing the Health Equity Gap in CMS Clinician Quality Programs in section IV.A.1.d. of this rule.

(a) Basis and Scope

At § 414.1300, we previously codified the basis and scope of the MIPS and APMs. In order to support the continued application of voluntary reporters, we propose to revise the basis and scope at § 414.1300(a)(2) to remove reference to section 1848(a) of the Act—Payment for Physicians' Services Based on Fee Schedule and instead redesignate the text at § 414.1300(a)(3) to § 414.1300(a)(2) to state section 1848(k)—Quality Reporting System. At § 414.1400(a)(3), we also propose to add new language to state section 1848(m)—Incentive Payments for Quality Reporting.

(b) MIPS Value Pathways and APM Performance Pathway

We recognize that the transition to MVPs will take time and we will continue to evaluate the readiness of clinicians in making this transition, while balancing our strong interest in improving measurement and making MIPS more focused on value.

As discussed in section IV.A.3.b. of this proposed rule, for MIPS Value Pathways (MVPs) we propose:

- To define who can report MVPs, through the term MVP Participant.
- A delay to the CY 2023 MIPS performance period/CY 2025 MIPS payment year: MVP implementation and subgroup reporting timelines. Beginning in the CY 2025 MIPS performance period/CY 2027 MIPS payment year, multispecialty groups would be required to form subgroups in order to report MVPs.
- An introductory set of 7 MVPs to be available beginning with the 2023 performance period.
- MVP reporting requirements that account for the four MIPS performance categories.
- During the CY 2023 and CY 2024 performance periods, voluntary subgroup reporting within MIPS limited to reporting through MVPs or the APP. For the MIPS program, eligibility, special status determination, and QP determination would continue to be determined at the group level for subgroup participants. Subgroup performance will be assessed at the subgroup level for three performance categories (the quality, cost, and improvement activities performance categories) and will be assessed at the group level for one performance category (the Promoting Interoperability performance category). Additionally, subgroups will continue to be included in group level reporting but will receive scores separate from their affiliated group.
- MVP scoring policies closely align with those used in traditional MIPS, with few exceptions.
- MVP scoring policies including policies for scoring administrative claims measures, including population health measures, scoring only the cost measures specified in the MVP, assigning 20 points for each medium-weighted and 40 points for each high-weighted improvement activity specified in the MVP, scoring subgroups on their affiliated group's data for the Promoting Interoperability performance category, reweighting performance categories for subgroups in certain circumstances, and requirements that the quality performance category be scored with few exceptions for reweighting.
- To provide comparative feedback within performance feedback, comparing the performance of like clinicians who report on the same MVP.

We also discuss in section IV.A.3.b. of this proposed rule, future considerations and goals of the MIPS program:

- We request comment on the timeline to sunset traditional MIPS in the future, and to eventually make MVP reporting mandatory. *Note: we are referring to the established MIPS participation options collectively as traditional MIPS (85 FR 84844).*
- Through the MVP development work, gradually implement MVPs for all specialties and subspecialties that participate in the program.

As discussed in section IV.A.3.c. of this proposed rule, for the APM Performance Pathway, to create stability within the APP, we are not proposing any major changes to the APP.

(c) Other MIPS and APM Policies

We are proposing the following provisions for MIPS beginning with the 2022 performance period:

- As discussed in section IV.A.3.d. of this proposed rule, for the MIPS Performance Measures and Activities, we propose:

++ In section IV.A.3.d.(1) of this proposed rule, for the quality performance category, to maintain the data completeness criteria threshold at 70 percent for the 2021 and 2022 MIPS performance periods (2023 and 2024 MIPS payment years); establish the data completeness criteria threshold at 80 percent for the 2023 MIPS performance period (2025 MIPS payment year); extend the availability of the CMS Web Interface as a collection and submission type for the 2022 MIPS performance period; establish a set of 195 MIPS quality measures; and seek public comment through a request for information (RFI) regarding the draft COVID–19 Vaccination by Clinicians measure specifications.

++ In section IV.A.3.d.(2) of this proposed rule, for the cost performance category, to establish 5 new cost measures for implementation into MIPS, which adds to the 2 global or population-based measures and 18 episode-based measures.

In section IV.A.3.e.(2) of this proposed rule, in regard to calculating the final score, we propose formulas for the complex patient bonus with two separate components (one for medical complexity and one for social complexity) and an overall cap of 10 bonus points. Lastly, we propose

updating the formulas for the bonuses to base them on standardized scores and to reward those who fall in higher quintiles and not reward those who fall below a cut-off point.

- As discussed in section IV.A.3.f. of this proposed rule, beginning with year 6 of MIPS (2024 MIPS payment year), the performance threshold must be either the mean or median of the final scores for all MIPS eligible clinicians for a prior period. We are proposing to establish the performance threshold using the mean and the 2017 performance period/2019 MIPS payment year data, which would result in a performance threshold of 75 points. In addition, for the 2024 MIPS payment year, the additional performance threshold must be set at either (1) the 25th percentile of the range of possible final scores above the performance threshold, or (2) the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to a prior period. We note that under section 1848(q)(6)(C) of the Act, the additional MIPS payment adjustment factors for exceptional performance are available through the 2024 MIPS payment year, making this the last year of the additional performance threshold and the associated additional MIPS payment adjustment factors for exceptional performance. We are proposing to establish an additional performance threshold of 89 points. This is the 25th percentile of actual final scores from the 2017 performance period/2019 MIPS payment year at or above 75 points.
- As discussed in section IV.A.3.h. of this proposed rule, for Third Party Intermediaries, we are proposing to modify third party intermediary requirements, remedial actions and termination policies. Specifically, beginning with the 2023 MIPS performance period/2025 MIPS payment year, QCDRs, qualified registries, and health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs, qualified registries, and, health IT vendors may also support the APP. We also propose to require QCDRs, qualified registries, health IT vendors, and CMS-approved survey vendors to support subgroup reporting beginning with the 2023 MIPS performance period/2025 MIPS payment year.
- As discussed in section IV.A.3.i. of this proposed rule, for Public Reporting on Compare Tools hosted by the U.S. Department of Health and Human Services (Compare Tools), we are proposing to publicly report clinician affiliations to certain types of facilities (for example, LTCHs, IRFs, etc.). We also seek comment through a RFI to inform the ways in which utilization data may be useful to patients and caregivers for their health care decisions. In order to give MIPS eligible clinicians time to familiarize themselves with MVPs and subgroup reporting, we are proposing to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVPs by 1 year, and begin publicly reporting subgroup-level performance information in PY 2024, on the compare tool hosted by the U.S. Department of Health and Human Services. We are also proposing to create a separate subgroup workflow that would allow subgroup performance information to be publicly reported in an online location that can be navigated to and from an individual clinician or group profile page. This also aligns with the historical approach to report performance information at the level that it is submitted.
- As discussed in section IV.A.4.b. and IV.A.4.c. of this rule, we are proposing a change to the APM Incentive Payment payee hierarchy to include payment to TINs associated with QPs during the payment year.

c. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Physician Quality Programs—Request for Information

We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As also detailed in the FY 2022 Hospital Inpatient PPS proposed rule (86 FR 25549 through 25554), as part of this modernization of our quality measurement enterprise, we are issuing this request for information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contains five parts:

- *Background.* This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- *Definition of Digital Quality Measures (dQMs).* This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- *Use of Fast Healthcare Interoperability Resources (FHIR®) for current electronic clinical quality measures (eCQMs).* This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- *Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.* This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- *Solicitation of Comments.* This part lists all requests for input included in the sections of this RFI.

(1) Background

As required by law, we implement quality measurement and value-based purchasing programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2020, we launched the CMS Quality Measure Action Plan.[133] One key goal of the plan is to improve the efficiency of quality measures by a transition to digital measures and use of advanced data analytics. Our objective is to use data and information as essential aspects of a healthy, robust healthcare infrastructure to allow for payment and management of accountable, value-based care and development of learning health organizations.[134] Consistent with the CMS Quality Measure Action Plan, we aim to move fully to digital quality measurement by 2025. We acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness, and therefore, the timeline for

[133] *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

[134] CMS Quality Measure Action Plan: *https://www.cms.gov/files/document/2021-cms-quality-conference-cms-quality-measurement-action-plan-march-2021.pdf.*

achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[135] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support Application Programming Interface (API) policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care providers, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[136] The ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[137] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[138]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan [QHP] on the Federally-facilitated Exchanges [FFEs]) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available certain data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule). These certain data include data concerning claims and encounters, with the intent to ensure access to their own health care information through third-party software applications. The rule also established new Conditions of Participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred if the hospital or CAH utilizes an electronic medical records system or other electronic administrative system which is conformant with the content exchange standard at 45 CFR 170.205(d)(2) (85 FR 25603). In the CY 2021 PFS final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce longstanding barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[139] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the

[135] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

[136] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

[137] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[138] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. Available at *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

[139] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

transition to digital quality measurement as described in this RFI.

(2) Definition of Digital Quality Measures

In this section we seek to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems.'' (85 FR 84845) In this RFI, we seek input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discuss one potential approach to developing dQM software in section IV.A.1.c of this proposed rule. In this section, we are seeking comment on the potential definition of dQMs in this RFI.

We also seek feedback on how leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability programs.[140] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the next section, CMS is currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. CMS intends to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

(3) Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past 2 years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR® (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides. Submitting data through FHIR APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

(4) Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to enable patients and caregivers to make

[140] eCQI Resource Center, *https://ecqi.healthit.gov/*.

informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We are requesting comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

(a) Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-Based APIs

We are considering targeting the data required for our quality measures that utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated implementation guides) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of electronic data submitted to the Hospital IQR Program with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We are seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We are also seeking feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcome comment on approaches for testing data quality and validity.

(b) Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s), and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions—

++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);

++ Calculate the measure score according to measure logic; and

++ Generate measure score report(s).

- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation, as well as diffusion of quality measurement and related quality

improvement and clinical tools through, for example, the use of open-source core architecture.

We seek comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We are also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

(c) Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Health IT vendors that meet the requirements of a Qualified Clinical Data Registries (QCDRs) and qualified registries that report quality measures for eligible clinicians in the MIPS program are potential examples [141] at section IV.A.3.g. of this proposed rule and can also support measure reporting.

We seek feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also seek feedback on the role data intermediaries can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

(d) Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across federal and state agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs [DoD/VA]); the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint federal, state, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We seek feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also seek to identify opportunities to collaborate with other federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

(5) Solicitation of Comments

As noted previously, we seek input on the future development of the following:

(a) Definition of Digital Quality Measures

We are seeking feedback on the following as described in section IV.A.1.c. of this proposed rule:

- Do you have feedback on the dQM definition?
- Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

(b) Use of FHIR for Current eCQMs

We are seeking feedback on the following as described in section IV.A.1.c. of this proposed rule:

- Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers? Please explain if you do not agree.
- Would access to near real-time quality measure scores benefit your practice? How so?
- What parts of the current CMS QRDA IGs cause the most burden (please explain the primary drivers of burden)?

[141] Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

• In what ways could a CMS FHIR Reporting IG be crafted to reduce burden on providers and vendors?

(c) Changes Under Consideration To Advance Digital Quality Measurement

Actions in Four Areas to Transition to Digital Quality Measures by 2025.

• We are seeking feedback on the following as described in section IV.A.1.c. of this proposed rule:

++ Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR Implementation Guides suggested for consideration?

++ How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

++ What are possible approaches for testing data quality and validity?

• We are seeking feedback on the following as described in section IV.A.1.c. of this proposed rule:

++ What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs)?

++ How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

• We seek feedback on the following as described in section IV.A.1.c. of this proposed rule:

++ What are key policy considerations for aggregation of data from multiple sources being used to inform measurement?

++ What role can or should data aggregators play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

• We seek feedback on the following as described in section IVA.1.c. of this proposed rule:

++ What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

++ We also seek to identify opportunities to collaborate with other federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

Commenters should consider provisions in the CMS Interoperability and Patient Access final rule (85 FR 25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 PFS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

d. Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information (RFI)

Persistent inequities in health care outcomes exist in the United States, including among Medicare patients.[142] In recognition of persistent health disparities and the importance of closing the health equity gap, we request information on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, providers, and patients. The following is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies (86 FR 25554 through 255561).

Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, is often associated with worse health outcomes.[143] [144] [145] [146] [147] [148] [149] [150] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[151] [152] [153] [154] [155] [156]

We are committed to achieving equity in health care outcomes for Medicare beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[157] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and

[142] Ochieng N., Cubanski J., Neuman T., Artiga S., Damico A. Racial and Ethnic Health Inequities and Medicare. KFF. February 2021.

[143] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[144] Lindenauer P.K., Lagu T., Rothberg M.B., et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013;346.

[145] Trivedi A.N., Nsa W., Hausmann LRM., et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014;371(24):2298–2308.

[146] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[147] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[148] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[149] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[150] Poteat T.C., Reisner S.L., Miller M., Wirtz A.L. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[151] Martino, S.C., Elliott, M.N., Dembosky, J.W., Hambarsoomian, K., Burkhart, Q., Klein, D.J., Gildner, J., and Haviland, A.M. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[152] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[153] Singh J.A., Lu X., Rosenthal G.E., Ibrahim S., Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[154] Rivera-Hernandez M., Rahman M., Mor V., Trivedi A.N. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[155] Joynt K.E., Orav E., Jha A.K. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[156] Tsai T.C., Orav E.J., Joynt K.E. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[157] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [158] We note this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity. [159] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of health disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[160] The CMS Quality Strategy [161] and Meaningful Measures Framework [162] also include elimination of racial and ethnic disparities as central principles. Our efforts aimed at closing the health equity gap to date have included providing transparency of health disparities, supporting providers with evidence-informed solutions to achieve health equity, and reporting to providers on gaps in quality as follows:

- The *CMS Mapping Medicare Disparities Tool* which is an interactive map which identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[163]
- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report,* which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[164]
- The *Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[165]
- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).
- *The CMS Innovation Center's Accountable Health Communities Model* which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews set of activities which can help hospital leaders reduce readmissions in diverse populations.[166]
- *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmissions Reduction Program (see 84 FR 42496 through 42500 for a discussion of using stratified data in additional measures).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM) [167] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [168] which have examined the influence of social risk factors on several of our quality programs. In this RFI, we discuss initiatives specific to further bridging the health equity gap within the MIPS track of the Quality Payment Program.

In Appendix 2: Improvement Activities of this proposed rule, we discuss a proposed improvement activity titled ''create and implement an anti-racism plan''. This improvement activity acknowledges it is insufficient to gather and analyze data by race, and document disparities by different population groups. Rather, it emphasizes systemic racism is the root cause for differences in health outcomes between socially defined racial groups. Further, we also propose to modify five existing improvement activities to address health equity. We note that some improvement activities within our current Inventory already aim to improve equity. We believe further modifying them can more explicitly link the activity to health equity without changing the core activity. In other cases, our proposals to modify an activity fundamentally shifts the activity to focus on health equity specifically.

Additionally, in section IV.A.3.e.(2) of this proposed rule, we are proposing to update the complex patient bonus formula. We specifically refer to ASPE's second report, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, which was publicly-released in May 2020.[169] The second report builds on the analyses included in the initial report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs. More specifically, the report has a 3-

[158] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[159] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[160] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[161] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[162] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[163] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[164] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[165] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

[166] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[167] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[168] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[169] Social Risk and Performance in Medicare's Value-Based Purchasing Programs. ASPE Second Report. May 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

pronged strategy approach to: Measure and report quality; set high, fair quality standards; and reward and support better outcomes for beneficiaries with social risk. As a part of this 3-pronged strategy, the report supports use of the complex patient bonus in MIPS, explaining that it is well supported because this policy gives additional points to clinicians with a higher share of medically and socially complex patients and does not lower the standard of care. Hence, although, ASPE's reports to Congress support the use of a complex patient bonus at the final score level, we respond to other findings reported in other literature studies by identifying ways to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients and to mitigate differences in resources that affect MIPS scores. Hence, the proposed formula is based on standardized scores and to reward only those clinicians who fall in higher quintiles in order to focus the bonus on those serving a higher proportion of more complex and vulnerable patients.

Lastly, we acknowledge that small practices within the MIPS program often face challenges in many ways. More specifically, as noted in section IV.A.3.e.(2) of this proposed rule, the Quality Payment Program gives an advantage to large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS (82 FR 53776). In response to the feedback on the potential burden on small practices, we have established special policies available for small practices including the small practice bonus and special scoring policies. For example, in the CY 2018 QPP final rule (82 FR 53682 through 53683), we established a significant hardship exception for small practices for the Promoting Interoperability performance category. To further alleviate the burden on small practices and reduce this disparity between large and small practices, we propose in section IV.A.3.d.(4) to automatically redistribute the Promoting Interoperability performance category weight for any small practice that does not submit data for the performance category, and in section IV.A.3.e.(2), we propose different redistribution weights for small practices.

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[170] We have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We are seeking public comment on two potential future expansions of the CMS Disparity Methods, including: (1) Future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection.

(1) Future Potential Stratification of Quality Measure Results by Race and Ethnicity

The Administration's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in federal programs. As summarized previously, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications. We are considering expanding the disparity methods to include stratification of the condition/procedure-specific readmission measures by race and ethnicity. The 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, outlines the racial and ethnic categories which may potentially be used for reporting the disparity methods, which we note are intended to be considered as social and cultural, and not biological or genetic.[171] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[172] Another example, the ''Race & Ethnicity—CDC'' code system in PHIN Vocabulary Access and Distribution System (VADS)[173] permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports aggregation and reporting using the OMB standard. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.[174] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using any of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in the Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS), as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. However, CMS currently does not consistently collect self-reported race and ethnicity for the Medicare program, but instead gets the data from the Social Security Administration (SSA) and the data accuracy and comprehensiveness have proven challenging despite capabilities in the marketplace via certified health IT products. Historical inaccuracies in federal data systems and limited collection classifications have also contributed to the limited quality of race and ethnicity information in our administrative data systems.[175] In recent decades, to address these data quality

[170] Centers for Medicare Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[171] Executive Office of the President Office of Management and Budget, Office of Information and Regulatory Affairs. Revisions to the standards for the classification of federal data on race and ethnicity. Vol 62. **Federal Register**. 1997:58782–58790.

[172] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[173] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

[174] See *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity.* For more information about the certification criterion for ''Demographics'' in the ONC Health IT Certification program, see *https://www.healthit.gov/test-method/demographics.*

[175] Zaslavasky A.M., Ayanian J.Z., Zaborski L.B. The validity of racial and ethnic codes in enrollment data for Medicare beneficiaries. Health Services Research, 2012 Jun (47) (3 Pt 2): 1300–21.

issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive racial and ethnic identification.[176] [177] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying white and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander (API) and American Indian/Alaskan Native race.[178] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with public and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection [179] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[180] The Office of the National Coordinator for Health Information Technology (ONC) included social, psychological, and behavioral standards in the 2015 Edition health information technology certification criteria (2015 Edition), providing interoperability standards (LOINC [Logical Observation Identifiers Names and Codes] and SNOMED CT [Systematized Nomenclature of Medicine—Clinical Terms]) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) z-codes, the alphanumeric codes used worldwide to represent diagnoses.[181]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirect estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on hospitals as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[182] Indirectly estimated data are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[183]

As described earlier, we previously supported the development of two such methods of indirect estimation of race and ethnicity among Medicare beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, state of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or API.[184] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[185]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C and D performance data for Medicare Advantage Plans by race and

[176] Filice C.E., Joynt K.E. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017; 55(12):e170–e176. doi:10.1097/MLR.0000000000000608.

[177] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[178] Zaslavsky A.M., Ayanian J.Z., Zaborski L.B. The validity of race and ethnicity in enrollment data for Medicare beneficiaries. Health Serv Res. 2012 Jun;47(3 Pt 2):1300–21

[179] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[180] *https://pubmed.ncbi.nlm.nih.gov/18567241/, https://pubmed.ncbi.nlm.nih.gov/30506674/,* Eicheldinger C., Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financ Rev.* 2008; 29(3):27–42. Haas A., Elliott M.N., Dembosky J.W., et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019; 54(1):13–23. doi:10.1111/1475–6773.13099.

[181] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[182] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[183] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[184] Bonito A.J., Bann C., Eicheldinger C., Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

[185] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research*, 54:13–23 and Bonito A.J., Bann C., Eicheldinger C., Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008.

ethnicity.[186] Validation testing reveals concordance of 0.88–0.95 between indirectly estimated and self-report among individuals who identify as White, Black, Hispanic and API for the MIBSG version 2.0 and concordance with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1[187] [188] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[189] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the hospital-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there remains the small risk of unintentionally introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We feel this amount of bias is considerably less than would be expected if stratified reporting was conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and soliciting comments about, the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

(2) Improving Demographic Data Collection

Currently self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[190] Collection and sharing of a standardized set of social, psychological, and behavioral data by clinicians, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[191] This could potentially include expansion to additional social factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We note that clinicians participating in the Medicare Promoting Interoperability Program must use certified EHR technology (CEHRT) that has been certified to the 2015 Edition of health IT certification criteria. As noted previously, the certification criterion for Demographics under the 2015 Edition (at 45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the United States Core Data for Interoperability (USCDI) (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified health IT products ability to collect social, psychological, and behavioral data (at 45 CFR 170.315(a)(15)). However, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability performance category. While the technical functionality exists to achieve the gold standard of data collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We are interested in learning about, and are soliciting comments on, current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status). Further, we are interested in potential challenges facing clinicians with collecting a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [192]) and standards for interoperable exchange (such as the United States Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria [193]). Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation of this demographic information into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported, information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

Therefore, based on our current and newly proposed policies, we seek comments on other efforts we can take within the MIPS program to further bridge the equity gap. We plan to continue working with ASPE, clinicians, the public, and other key stakeholders on this important issue to identify policy solutions to achieve the

[186] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[187] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[188] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[189] Haas, A., Elliott, M.N., Dembosky, J.W., et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13– 23. *https://doi.org/10.1111/1475-6773.13099.*

[190] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[191] The Office of the National Coordinator for Health Information Technology. United States Core Data for Interoperability Draft Version 2. 2021. *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

[192] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[193] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

goals of attaining health equity for all patients and minimizing unintended consequences. We look forward to receiving feedback on these topics and note for readers that responses to the RFI will not directly impact payment decisions. We also note our intention for additional RFI or rulemaking on this topic in the future. While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 PFS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance.

2. Definitions

At § 414.1305, we are proposing definitions of the following terms:

- Collection type (revision).
- Meaningful EHR user for MIPS (revision).
- MIPS determination period (revision).
- MIPS eligible clinician (revision).
- Multispecialty group (addition).
- MVP Participant (addition).
- Population health measure (addition).
- QCDR measure (addition).
- Single specialty group (addition).
- Special status (addition).
- Subgroup (addition).
- Submission type (revision).

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

3. MIPS Program Details

a. MIPS Eligibility

(1) MIPS Eligible Clinician Definition

In the CY 2017 Quality Payment Program final rule (81 FR77040 through 77041), we defined a MIPS eligible clinician at § 414.1305, as identified by a unique billing TIN and NPI combination used to assess performance, as any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act), a PA, NP, and CNS (as such terms are defined in section 1861(aa)(5) of the Act), a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act), and a group that includes such clinicians. We established at § 414.1310(b) and (c) that the following are excluded from this definition per the statutory exclusions defined in section 1848(q)(1)(C)(ii) and (v) of the Act: (1) QPs; (2) Partial QPs who choose not to report on applicable measures and activities that are required to be reported under MIPS for any given performance period in a year; (3) low-volume threshold eligible clinicians; and (4) new Medicare-enrolled eligible clinicians. In accordance with sections 1848(q)(1)(A) and (q)(1)(C)(vi) of the Act, we established at § 414.1310(b)(2) that eligible clinicians (as defined at § 414.1305) who are not MIPS eligible clinicians have the option to voluntarily report measures and activities for MIPS. Additionally, we established at § 414.1310(d) that in no case will a MIPS payment adjustment apply to the items and services furnished during a year by eligible clinicians who are not MIPS eligible clinicians, as described in § 414.1310(b) and (c), including those who voluntarily report on applicable measures and activities specified under MIPS. In this proposed rule, we are proposing to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to include certified nurse-midwives (as defined in section 1861(gg)(2) of the Act) and clinical social workers (as defined in section 1861(hh)(1) of the Act).

Section 1848(q)(1)(C)(i)(II) of the Act provides the Secretary with discretion, beginning with the 2021 MIPS payment year, to specify additional eligible clinicians (as defined in section 1848(k)(3)(B) of the Act) as MIPS eligible clinicians. Such clinicians may include physical therapists, occupational therapists, or qualified speech-language pathologists; qualified audiologists (as defined in section 1861(ll)(3)(B) of the Act); certified nurse-midwives (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); clinical psychologists (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietitians or nutrition professionals. Therefore, in the CY 2019 PFS proposed rule (83 FR 35883 through 35884), we proposed to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a PA, NP, CNS (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, clinical social worker (as defined in section 1861(hh)(1) of the Act), and clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act. In addition, we requested comments on specifying qualified speech-language pathologists, qualified audiologists, certified nurse-midwives, and registered dietitians or nutrition professionals as MIPS eligible clinicians beginning with the 2021 MIPS payment year.

After consideration of comments, we received we finalized to revise our proposal in the CY 2019 PFS final rule (83 FR 59722 through 59727) and amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a PA, NP, CNS (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 MIPS payment year, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; and a group that includes such clinicians.

In this proposed rule, we are proposing to amend § 414.1305 to revise the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to include certified nurse-midwives (as defined in section 1861(gg)(2) of the Act) and clinical social workers (as defined in section 1861(hh)(1) of the Act). The new definition would mean any of the following (excluding those identified at § 414.1310(b)): A physician (as defined in section 1861(r) of the Act); a PA, NP, CNS (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); beginning with the 2021 through 2023 MIPS payment years, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; beginning with the 2024 MIPS payment year, certified nurse-midwives (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); and a group that includes such clinicians.

In order to assess whether these additional eligible clinicians (certified nurse-midwives and clinical social workers) could successfully participate in MIPS, we evaluated whether there would be sufficient measures and activities applicable and available for each of the additional eligible clinician types. We finalized in the CY 2018 Quality Payment Program final rule (82 FR 53780), that having sufficient measures for the quality performance category, means having sufficient measures applicable and available that we can calculate a quality performance category percent score for the MIPS eligible clinician because at least one quality measure is applicable and available to the clinician. For the improvement activities performance category, we believe that all MIPS eligible clinicians will have sufficient activities applicable and available, as they are broadly applicable. We focused our analysis on the quality and improvement activities performance categories because these performance categories require submission of data. For the Promoting Interoperability performance category, we do not believe that clinical social workers would have sufficient and available measures available. We refer readers to section IV.A.3.d.(4)(h) of this proposed rule, where we are proposing a policy to automatically assign a zero percent weighting for the Promoting Interoperability performance category for the clinical social workers. However, for the certified nurse-midwives we do believe they would have sufficient and available measures as many of them have participated in the Medicaid EHR Incentive Program and have experience with the adoption or use of CEHRT (81 FR 77243). Therefore, the certified nurse-midwives score would not be reweighted for the Promoting Interoperability performance category. However, it should be noted that if a clinician believes they are under undue hardship they may apply for a Hardship Application. We did not focus as part of our analysis on the cost performance category because we are only able to assess cost performance for a subset of eligible clinicians—specifically, those who are currently eligible as a result of not meeting any of the current exclusion criteria. We do not believe there are cost measures that would apply to the care that clinical social workers or certified nurse-midwives tend to provide. The current set of episode-based measures in the cost performance category focuses on a range of acute inpatient medical conditions and procedures, and the two population-based cost measures assess inpatient and primary care. Therefore, we anticipate the cost category would be reweighted for the majority of these clinician types. The impact of the cost performance category for these additional eligible clinicians would continue to be considered but is currently not a decisive factor for successful participation in MIPS. From our analysis, we found that improvement activities would generally be applicable and available for each of the additional eligible clinician types. For the quality performance category, we found that the additional eligible clinician types would have sufficient MIPS quality measures applicable and available. Since the CY 2019 PFS final rule, we have increased the quality measures that we believe are applicable to clinical social workers to 15 quality measures, which includes 2 outcome measures and 8 high priority measures. In the CY 2021 PFS final rule (85 FR 85069 through 85071), we finalized a Clinical Social Worker Specialty Measure Set. For certified nurse-midwives we believe there are 7 quality measures which includes 2 outcome measures and 5 high priority measures available for reporting in performance year 2022. In Appendix 1, Table Group BA of this proposed rule, we are proposing a Certified Nurse-Midwives Specialty Set. In addition, we received correspondence from the clinical social workers national associations requesting to be included in MIPS. Finally, amending the definition of a MIPS eligible clinician to include clinical social workers and certified nurse-midwives would align with § 414.1305 definition of an eligible clinician utilized by MIPS APMs for eligibility determinations.

We request comments on our proposal to amend § 414.1305 to modify the definition of a MIPS eligible clinician, as identified by a unique billing TIN and NPI combination used to assess performance, to mean any of following (excluding those identified at § 414.1310(b)): For the 2019 and 2020 MIPS payment years, a physician (as defined in section 1861(r) of the Act); a PA, NP, or CNS (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); for the 2021 through 2023 MIPS payment years, a physical therapist, occupational therapist, qualified speech-language pathologist; qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act); clinical psychologist (as defined by the Secretary for purposes of section 1861(ii) of the Act); and registered dietician or nutrition professional; for the 2024 MIPS payment year and future years, a certified nurse-midwives (as defined in section 1861(gg)(2) of the Act); clinical social workers (as defined in section 1861(hh)(1) of the Act); and a group that includes such clinicians.

(2) MIPS Performance Period

In the CY 2019 PFS final rule (83 FR 59745 through 59747) we finalized to amend § 414.1320(d)(1) that for purposes of the 2022 MIPS payment year and future years, the performance period for the quality and cost performance categories would be the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. In addition, we finalized at § 414.1320(d)(2) that for purposes of the 2022 MIPS payment year and future years, the performance period for the improvement activities performance category would be a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

In the CY 2021 PFS final rule (85 FR 84873), we finalized the performance period for the quality and cost performance categories at § 414.1320(d)(1) as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). However, the quality, cost, and improvement activities performance period for the 2022 MIPS payment year, formerly at § 414.1320(d), was inadvertently deleted, and the amended language regarding administrative claims measures was not expressly retroactive. We recognize that the application of this policy for the 2020 MIPS performance period would be retroactive. To the extent that the application of this policy for the 2020 MIPS performance period would be retroactive, section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. We believe that failure to reinstate the inadvertently deleted language retroactively would be contrary to the public interest because the performance period establishes the timespan for the

collection of performance data, assessment of performance, and computation of the MIPS payment adjustment, to which clinicians have already committed valuable time and resources. In addition, many of the MIPS policies such as the MIPS determination period and the low-volume threshold determinations utilize the performance period as an integral part of the policy, without which we would be unable to operate the MIPS program as required by statute. Therefore, we are requesting comments on our technical amendment to reinstate the inadvertently deleted language, with a modification to state ''For purposes of . . .'' rather than ''Beginning with . . .''. The proposed text would state, for purposes of the 2022 MIPS payment year, the performance period for: (1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year; and (2) The improvement activities performance categories is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Lastly, we propose to redesignate current § 414.1320(d) through (g) to § 414.1320(e) through (h), respectively.

(3) Modifications to Small Practice Groups Reporting Medicare Part B Claims Measures

In the CY 2019 PFS final rule (83 FR 59753), we established that beginning with the 2019 performance period, Medicare Part B Claims would be an available collection type and submission type for the quality performance category for small practices reporting as individuals or a group. We also stated that in circumstances where only Medicare Part B claims were submitted, that we intended on calculating the quality performance category for the practice as both a group and as individuals and apply the quality performance category score that is the greater of the two. We considered requiring an election for assessment as a group but believed this would be unduly burdensome on small practices (83 FR 59752).

Although we stated we would take the highest of the individual or group score for MIPS eligible clinicians in small practices, we now recognize that this policy has had an unintended impact for clinicians in a small practice who did not submit Medicare Part B quality claims and would not otherwise be eligible for MIPS. Once we receive a Medicare Part B submission, both an individual score and a group score is created. Once a group score is created, a clinician who was individually excluded from MIPS for being under the low-volume threshold, may now be eligible if the group exceeds the low-volume threshold. These clinicians would receive the MIPS final score based on the Medicare Part B submissions, even if the group did not intend to report to MIPS as a group. While we still perform an analysis to only provide to the clinicians the highest final score available, clinicians who are only MIPS eligible by the act of exceeding the low volume threshold as a group are receiving final scores that are unintended. This issue will continue to be further exacerbated as the performance threshold continues to increase, so does the likelihood that a final score from the quality performance category alone (or quality and cost as cost does not have submission requirements) could be below the performance threshold for a group. We therefore now believe it is important for the group to clearly signal its intention to report to MIPS as a group before we expand potential eligibility to other members of the group.

We have existing policies under MIPS that require clinicians to indicate to us when to utilize a group submission. For example, in the CY 2019 PFS final rule (83 FR 59862), we stated that submission of data on improvement activities or Promoting Interoperability measures would indicate that the clinicians in that group wanted to be scored as a group for the purposes of facility-based measurement. Therefore, we believe a similar policy would be appropriate for small practices to indicate they wish to submit Medicare Part B claims for a group quality performance category score. We are proposing that starting with the CY2022 MIPS performance period/2024 MIPS payment year, small practices, excluding those participating in MIPS as part of a virtual group, must submit data as a group in any performance category to indicate that they wish to be scored as a group for Medicare Part B claims. This means a group would need to submit data as a group to the improvement activities, Promoting Interoperability performance categories, or to the quality performance category via another submission mechanism as a group (for example, a group that submits MIPS CQMs in addition to Medicare Part B claims data). Once the group submits data to MIPS as a group, we would consider any available Medicare Part B claims measure submissions in calculating their quality performance category score.

We believe using the choice to submit data as a group would indicate the group's intention to participate and be measured as a group. The proposal would preserve and respect the choices made by clinicians and groups by not inadvertently expanding eligibility unwittingly to other clinicians. We note that this proposal would not apply to small practices participating in MIPS as part of a virtual group, because clinicians signal their intent to be scored as a virtual group through the virtual group election process.

We request public comments on our proposal.

b. Transforming MIPS: MIPS Value Pathways

(1) Overview

We are moving to MIPS Value Pathways (MVPs) to improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to facilitate movement into APMs (84 FR 40732 through 40734 and 85 FR 84844 through 84845). We intend to promote high value care by paying for health care services by linking performance on cost, quality, and the patient's experience of care. The MVP framework will move MIPS forward on the path to value by connecting the MIPS performance categories, better informing and empowering patients to make decisions about their healthcare, and by helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability.

Stakeholders have supported the MVP framework and our MVP guiding principles, which aim to reduce complexity and burden, move towards more meaningful measurement, capture the patient voice, and move to higher value care (84 FR 62946 and 85 FR 84845). We believe MVP reporting will reduce selection burden with choosing MIPS quality measures and improvement activities to submit; reduce reporting burden by requiring submission of fewer MIPS quality measures than the traditional MIPS participation method; and further align across performance categories the measures and activities identified by specialists and patients as being meaningful and relevant. We believe MVPs developed in coordination with stakeholders with an established process in which clinician and patient perspectives are incorporated (85 FR 84850) can result in more meaningful performance data, reduced complexity

of the MIPS program, and lowered clinician burden to participate.

MVPs will make MIPS more meaningful by allowing a more cohesive participation experience; by standardizing performance measurement of a specialty, medical condition, or episode of care; and reducing the siloed nature of the traditional MIPS participation experience. We intend for MVPs to drive value and help clinicians and practices prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructure components (measurement tracking, performance improvement processes, interoperability and data information systems) that align with the MIPS performance categories and gain experience with cost measurement (84 FR 40733). Performance measure reporting for specific populations, such as in MVPs, encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. The experience with MVPs, in which there is aligned measurement of quality (of care and experience of care) and cost, continuous improvement/innovation within the practice, and efficient management and transfers of information will help clinicians deliver higher value care and remove barriers to APM participation. Combining linked performance measures and activities with more standardization of measures in MVPs will produce data that can better assist patients in comparing clinician performance and selecting clinicians from which to seek care.

Further, MVPs will provide multispecialty groups a way to report performance information which is meaningful to various specialties and teams within the group through the proposed future subgroup reporting option discussed in section IV.A.3.b.(3) of this proposed rule. Multispecialty groups, especially those groups with many specialties and clinicians, often provide an array of services that may not be captured in a single set of measures or in a single MVP. Subgroup reporting would allow increased comprehensiveness of multispecialty group performance data as more services, including specialty services, can be represented since a group and subgroup may be able to report more than one MVP. The subgroup performance data would provide more detailed and clinically relevant information than the group reporting option available under traditional MIPS. The subgroup performance data would also assist patients in selecting clinicians because the data would be more relevant and specific to the care provided by clinicians in the subgroup. We refer readers to section IV.A.3.b.(3) of this proposed rule for our proposals on MVP subgroup reporting.

Under traditional MIPS, we understand clinicians and their administrative staff spend time and resources sifting through large inventories of measures and activities and depending upon how their practice decides to participate, may ultimately submit unrelated measures and activities. While we have attempted to streamline this process through the development of quality specialty sets and user-friendly tools on our website (see measure selection tool at *https://qpp.cms.gov/mips/explore-measures?tab=qualityMeasures&py=2020#measures*), we still hear concerns from stakeholders about not having relevant measures and activities (January 7, 2021 Town Hall (85 FR 74729 through 74730) feedback). MVPs are being developed to focus on a given specialty, condition, and/or episode of care (85 FR 84851). As more MVPs become available, we intend to continue to offer tools to clinicians that meet the real needs of the users, based on human-centered design considerations [194] that will be helpful as they select and submit MVPs, such as including MVPs in the MIPS shopping cart. MVPs would also bring the opportunity for clinicians to participate as subgroups, which would address the issue that exists under traditional MIPS of limited multispecialty group performance reporting. Subgroups formed within a multispecialty group would be able to submit performance measures and activities that are specific to their services and the associated patient conditions or health priorities. Additionally, clinician performance data, which is more meaningful to the services provided by subgroup participants, will be more readily available to be used by clinicians to improve quality and value of their services. As more clinicians have applicable MVPs, the performance data available to patients will expand, and in the future, information for specialists in multispecialty groups will become more available on our Compare Tools, enabling patients to make more informed choices for their care.

We continue our efforts to improve the healthcare of Medicare patients by allowing clinicians to focus on providing care for their patients and report on measures and activities that best reflect their care. As we propose MVP implementation policies, we are considering the critical factors that will contribute to and demonstrate MVP success and the characteristics of the overall MVP portfolio. We look forward to continuing to work with stakeholders to improve the program and implement the vision of MVPs.

(2) MVP Framework and Implementation Considerations

As discussed in the CY 2020 PFS proposed and CY 2021 PFS final rules (84 FR 40732 through 40734, 85 FR 50279 and 85 FR 84844 through 84845 respectively), our MVP framework calls for linking the MIPS quality, cost, and improvement activities performance categories with a foundation of the Promoting Interoperability and population health claims-based measures. We are considering how to best implement an MVP portfolio that balances our MVP goals for transformative change and our five MVP guiding principles (85 FR 84845) within current capabilities. We note there are constraints related to the ability to implement significant program changes including statutory restrictions on the structure of MIPS, and limitations of the current quality and cost measure inventory.

(a) MVP Transition

Stakeholders have urged us to allow sufficient transition time for MVP implementation (85 FR 84859). We recognize that the complete transition to MVPs should account for clinicians' readiness for change, the current state of measure development, CMS's operational limitations, and stakeholder capacity for developing and implementing MVPs. We refer readers to our 2022 PFS Proposed Rule Timeline: Transition from Traditional MIPS to MVPs graphic at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1501/2022%20PFS%20Proposed%20Rule_MVP%20Timeline%20Graphic.pdf* and section IV.A.3.b.(2)(d) of this proposed rule for discussion of our MVP transition timeline which outlines our response to stakeholder concerns about adequate transition time and our plans for a gradual incremental transition to MVPs.

Stakeholders have largely supported our MVP goals, but a few have voiced concerns regarding whether our goals to drive value, reduce burden, and derive comparative data can be achieved via the MVP framework (85 FR 84845 through 84847). We have received comments stating MVPs should utilize more innovative approaches (85 FR

[194] *https://qpp.cms.gov/about/hcd-research.*

84850). Regarding utilization of innovative approaches, we note that the statutory requirements at section 1848 of the Act may constrain our ability to adopt certain changes. These requirements include but are not limited to: The use of four MIPS performance categories (quality, cost, improvement activities and Promoting Interoperability); setting the performance threshold; the call for measures and annual quality measure selection process; and the prescribed performance category weights. Conversely, the statute does provide limited flexibilities in some other areas, so we are interested in exploring any existing MIPS flexibilities that will assist us in implementing MVPs. As we begin MVP implementation, the portfolio of MVPs will be developed with a focus on our end goals while adhering to statutory requirements.

We request public comment on innovative ideas that can help achieve our desired MVP results. MVPs aim to improve value, reduce burden, help patients compare clinician performance to inform patient choice in selecting clinicians, and reduce barriers to movement into APMs.

Additional performance measures that support targeted MVP clinical areas may be needed to develop MVPs for all clinicians and to ensure they have meaningful measures, which include the patient perspective, care outcomes, and to support linkages between cost and quality. In section IV.A.3.d.(2)(c) of this proposed rule, we seek comment on challenges that stakeholders may encounter, and ways to ensure that stakeholder-developed cost measures meet certain standards and are consistent with the goals of MIPS and MVPs. Additionally, in section IV.A.1.(d) of this proposed rule, we discuss our request for information on closing the health equity gap in CMS clinician quality programs, potential future stratification of quality measures, and request comments on other efforts we can take within the MIPS program to further bridge the health equity gap.

While we aim to shift towards the ideal MVP state, we have data submission limitations slowing our ability to reach our objective of reporting burden reduction. Ultimately, we envision that the future goal of the Quality Payment Program, particularly with MIPS and MVPs, is to ensure there is more granular data available for patients, clinicians, and other stakeholders. We envision an end state where technology will allow for the submission of discrete data elements. CMS will be able to calculate measure performance for clinicians, subgroups, and groups, rather than having measure performance aggregated and calculated at a group or subgroup level prior to reporting. We anticipate more granular data will be available for patients, clinicians, and other stakeholders through an approach of future mandatory subgroup reporting (as discussed in section IV.A.3.b.(3)(h) of this proposed rule). We also look forward to broad use of standards-based APIs that leverage the FHIR standard within EHRs (as discussed in section IV.A.3.d.(4)(j)(i) of this proposed rule) and the creation and use of dQMs (as discussed in section IV.A.1.c.(5) of this proposed rule). See section IV.A.1.c. of this proposed rule for our Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR®) in Physician Quality Programs RFI, which addresses: (1) A refined definition of digital quality measures, (2) the use of FHIR® for eCQMs, and (3) changes under consideration to advance digital quality measurement with the intent of transitioning to digital quality measures by 2025.

We held a Town Hall meeting on January 7, 2021(recording available at *https://www.youtube.com/watch?v=7CjQeuD3eFE&feature=youtu.be*) to obtain stakeholder feedback on MVP considerations for MVP design and implementation (85 FR 74729 through 74730). We have received commenter concerns from previous MVP rulemaking and MIPS MVP Town Hall about fragmented care under specialty focused MVPs with a few commenters voicing support for a care-coordination focus. We do not want to restrict MVP development to only the concepts already presented. For example, we envision that some MVPs would be reported primarily by a single specialty and other MVPs would include measures and activities relevant to a broad range of clinicians. We are interested in MVPs that target a focused episode of care, as well as MVPs that measure the patient journey and care experience longitudinally. We would like to explore how MVPs could best measure the value of multi-disciplinary team-based care. See section IV.A.3.b.(4)(b)(i)(A) of this proposed rule, for discussion of MVP development areas and broad and team-based holistic MVP approaches.

Our approach to developing the portfolio of MVPs must balance objectives for having MVPs available for the diverse range of MIPS eligible clinicians, the variety of health conditions affecting Medicare patients, and the patient's needs for relevant, meaningful information. We seek stakeholder feedback on the types of MVPs and quality and cost measures required to meet those objectives.

We request public comment on the concepts outlined above.

(b) MVP Guiding Principles

(i) Overview of the Guiding Principles

In the CY 2021 PFS final rule (85 FR 84845 through 84849), we updated the MVP guiding principles from the CY 2020 PFS proposed rule (84 FR 40734) to incorporate RFI comments and the evolution of the MVP framework.

The guiding principles for MVPs are as follows:

1. MVPs should consist of limited, connected complementary sets of measures and activities that are meaningful to clinicians. This will reduce clinician burden, align scoring, and lead to sufficient comparative data.

2. MVPs should include measures and activities that result in providing comparative performance data, which is valuable to patients and caregivers in evaluating clinician performance and making choices about their care. MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.

3. MVPs should include measures selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included, to encourage performance improvements in high priority areas.

4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

5. MVPs should support the transition to digital quality measures.

(ii) Implementation of MVP Guiding Principles and Practical Considerations

The MVP guiding principles will help move us towards our goals of transforming healthcare. Stakeholders have supported the guiding principles and have indicated their interest in further understanding how we intend to implement the MVP Guiding Principles (85 FR 84845). As we introduce MVPs and address operational policies, we are focused on the guiding principles and the concrete steps needed to implement the principles at both the individual MVP level and the MVP portfolio level. We acknowledge certain tensions between our intent to simplify MIPS through increased performance measurement standardization versus clinician's desire for flexibility and choice of performance measure and

activities. We also acknowledge tensions between our intent to obtain comparable clinician performance data and include meaningful measures for all clinician types and specialties while minimizing burden. We want to provide patients with valuable and comparable clinician performance data to assist patients and caregivers when selecting a clinician or group. At the same time, we must consider clinician burden and performance measurement aspects such as measure reliability and attribution methodologies. The availability of the subgroup reporting option, proposed in section IV.A.3.b.(3) of this proposed rule, would move in the direction of facilitating more comprehensive performance data for multidisciplinary groups.

We want to connect cost measures to quality measures and improvement activities in newly developed MVPs as stated in guiding principle 1 (85 FR 84849 through 84854). However, as we look to develop MVPs for all MIPS eligible clinicians, we are hampered by the limited availability of cost measures. Also, the siloed cost measures and quality measures development processes can present a degree of challenge in forming cohesive measure sets in MVPs as cost and quality measures are often developed independently of one another, addressing different patient populations and care conditions. Because improving value requires the ability to measure quality and cost of care, we are concerned with the limited number of cost measures currently available. We are proposing five cost measures for implementation into MIPS in section IV.A.3.d.(2)(b) of this proposed rule. We also want to expand our ability to have cost measures available for MVPs. We refer readers to section IV.A.3.d.(2)(c) of this proposed rule, which discusses our proposal for external cost measure development by stakeholders.

Given these tensions and challenges, we plan to continue balancing the MVP framework approaches and our incremental MVP introduction while focusing on our overarching goals and considerations of current and future developments to help us implement the MVP guiding principles.

(iii) Implementing MVP Guiding Principles

In this rule we propose several policies that begin to implement the MVP guiding principles. We also outline several challenges to implementing the guiding principles and, in multiple sections of this rule, request public comment to guide us in future rulemaking.

We are proposing seven initial MVPs in section IV.A.3.b.(4)(c) of this proposed rule for implementation in CY 2023 performance period. The proposed MVPs contain related cost and quality measures and improvement activities. The proposed MVPs also limit the number of quality measures and improvement activities from which clinicians would choose to report and require fewer reported quality measures than in traditional MIPS. Both cost and population health measures are calculated from claims data and do not have to be submitted by clinicians. The proposed MVPs represent concrete progress toward implementing the guiding principles.

For example:

- Requiring the submission of fewer quality measures and a lessened measure selection effort reduces clinician burden.
- Hearing from stakeholders ensures that measures are relevant to clinicians.
- The limited numbers of cost and quality measures in an MVP will support greater numbers of clinicians being scored on the same measures, leading to improved comparative data.
- The MVPs address a Meaningful Measure domain and contain measures that are clinically appropriate to the clinicians and care settings for whom the MVP is focused.

In section IV.A.3.b.(5) of this proposed rule, we implement the guiding principle 1 concept to ''align scoring'' by proposing MVP scoring policies that mirror traditional MIPS scoring in MVPs while moving away from earlier transitional policies that may have masked performance differences or inflated performance scores. Our scoring policies aim to spur improvements, drive higher value care, and promote fairness. We propose to maintain scoring policies finalized in traditional MIPS for MVPs to leverage meaningful scoring policies and retain stable scoring for APM Participants.

The subgroup reporting option outlined in section IV.A.3.b.(3) of this proposed rule operationalizes guiding principle 2 and, as noted above, will increase the number of clinicians reporting and better serve specialty clinicians who want to be scored on performance measures relevant to their specialty and services provided. Public reporting of MVP and subgroup information as proposed in section IV.A.3.b.(3)(g) of this rule will further guiding principle 2 goal of providing comparative information that is valuable to patients and caregivers.

We request public comment on innovative approaches to measuring value that might include APM performance measurement approaches and using a single patient population both for MVP cost and quality measures in the future.

We have also discussed our intent to provide more robust clinician performance data feedback for MVP submissions (84 FR 40733 through 40734). Receiving more meaningful feedback through MVPs would help prepare clinicians to meet APM goals for managing patient populations. While clinicians support more robust data feedback, the current timing of data submission after the performance year ends is a barrier to providing more timely data feedback to clinicians during the performance year. As we move to dQMs and utilization of standards-based APIs to retrieve data from provider data sources, earlier, more frequent reporting, and more granular data (as in subgroup reporting) may be possible without additional clinician burden, allowing us to provide more timely clinician performance data feedback. See section IV.A.3.b.(5)(d) of this proposed rule for discussion of MVP clinician data feedback.

During our January 7, 2021, MVP Town Hall meeting we sought feedback on how to best coordinate and align MVPs and APMs (85 FR 74729 through 74730). A few Town Hall commenters suggested that MVPs serve as a long-term performance-based option to improve physicians' experience in MIPS and as an on-ramp for clinicians from MIPS to APMs. A few commenters supported the development of MVPs for areas where APMs are absent, with a few stakeholders supporting an initial focus on developing MVPs around existing specialty measures sets before transitioning the MVP into a bridge for clinicians who do not have an applicable APM. We also received a comment that there may be scenarios in which it may be challenging to use the same measures in an MVP as an APM, as the commenter stated APM participants have more legal flexibility and APM models often use Innovation Center waiver authority (section 1115A of the Act). We continue to explore the ideal MVP relationship with APMs, and how to best drive value and align performance measurement given differences in payment, performance measurement methods (such as prospective and retrospective measure attribution), patient population (all payer versus fee-for-service), and data submission.

While the proposals in this proposed rule referenced above demonstrate important progress toward realizing the MVP guiding principles, challenges remain for CMS and stakeholders in

developing a portfolio of MVPs that fully implement the guiding principles and achieve our vision for MVPs. As we propose to introduce MVPs and implement our guiding principles, we continue to strive to fully implement MVPs and the overall portfolio to drive value, obtain comparative performance data, and elevate the patient voice while reducing clinician burden.

(c) MVP Participant

(i) MVP Participant Definition

As we look ahead to implementing MVPs, we believe it is important to clearly define who can participate in MIPS through MVPs. We believe that defining MVP participation will help stakeholders better understand how our policies affect them, as well as provide clarity and simplicity for readers.

At § 414.1305 we have previously finalized definitions for a MIPS eligible clinician, group, and APM Entity. While we are not proposing to change these definitions, and are using these existing terms, we seek to clarify who can participate in MVPs. We are proposing a new opportunity for clinicians to participate in MVPs, as a subgroup. We refer readers to section IV.A.3.b.(3) and § 414.1305 of this proposed rule, where we propose the definition for a subgroup. In addition, we believe it would be helpful to distinguish the types of groups that participate in MIPS, and how they could participate in MVPs. Therefore, we refer readers to section IV.A.3.b.(3) and § 414.1305 of this proposed rule, where we propose definitions for single specialty group, multispecialty group, and special status, to provide further clarity for stakeholders as they seek to understand how they can participate in MVPs.

In keeping with MVPs broader aim of cohesive participation, at § 414.1305 we are proposing the term MVP Participant to mean: An individual MIPS eligible clinician, multispecialty group, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2025 MIPS performance period/2027 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. The proposed definition of MVP Participant accounts for the gradual transition to requiring multispecialty groups to form subgroups if they want to report MVPs. We believe this is important because multispecialty groups report on the same set of measures, which may not be relevant or meaningful to all specialists that participate within the multispecialty group, to make improvements in the care they provide to patients. We refer readers to section IV.A.3.b.(2)(d)(ii) of this proposed rule for discussion of subgroup implementation, including multispecialty groups forming subgroups to report MVPs beginning with the CY 2025 MIPS performance period/2027 MIPS payment year. Table 30 serves to summarize our proposals, specifically which MVP Participants can report an MVP in the future:

TABLE 30: Who Can Report MVPs

Who Can Report MVPs	
CY 2023- CY 2024 MIPS Performance Period	Individual MIPS eligible clinicians, single specialty groups, multispecialty groups*, subgroups, and APM Entities.
CY 2025 MIPS Performance Period, and Future Years	Individual MIPS eligible clinicians, single specialty groups, subgroups*, and APM Entities.

**Multispecialty Groups would be required to report as subgroups in order to report MVPs beginning with the CY 2025 MIPS performance period/2027 MIPS payment year.*

We recognize that in some limited instances, there are specific policy proposals that are more narrow or expansive than the term MVP Participant allows for. In those cases, we will continue to clarify which specific participants a given policy applies to, rather than using the new term. For example, if we have policies regarding what is required during subgroup registration, as discussed below, we would specify that these policies would be specific to subgroups rather than use the term MVP Participants. In another example, in section IV.A.3.b.(5)(b)(iv) of this proposed rule, we propose Promoting Interoperability performance category scoring policies that apply to individual MIPS eligible clinicians, groups, and APM Entities, but do not apply to subgroups. In this example, we would clarify that the policy applies to MVP Participants, except subgroups. In addition, if we determine a given policy proposal is applicable to groups, regardless of whether they are single specialty or multispecialty, we may simply refer to them as groups. We believe stakeholders would welcome the simplicity that using the term MVP Participant would provide. It is an important step forward for the program that would promote clarity and consistency of policy drafting and compliance by stakeholders. We request public comment on the proposal.

(ii) Opt-In Participants, Voluntary Participants, and Virtual Groups

As discussed above, we are proposing that for the implementation of MVPs, certain clinicians would not be able to participate. These include, voluntary reporters, opt-in eligible clinicians, and virtual groups, who would have their participation in MVPs delayed. We refer readers to section IV.A.3.b.(3)(d)(iv)(C) of this proposed rule for discussion of the participation rates of opt-in and voluntary participants. Similar to our request for comments on whether Opt-In and voluntary participants should be allowed to join subgroup reporting in a future state, we also request comment on whether opt-in participants, voluntary participants, and virtual groups should be allowed to report MVPs as MVP Participants in a future state.

(d) MVP and Subgroup Implementation Timeline

(i) MVP Implementation Timeline

Since the finalization of the MIPS Value Pathways framework through the CY 2020 PFS final rule (84 FR 62946 through 62949), stakeholders have provided feedback on our implementation timeline through multiple methods, including public comment through rulemaking, meetings, and the MVP Town Hall that held in January 2021. Associated resources related to the MVP Town Hall are available for stakeholder review through the Quality Payment Program Resource Library are available at *https://qpp.cms.gov/resources/webinars*.

Through the MVP Town Hall, we have heard stakeholders encourage MVPs be implemented through a

gradual process that provides MVP participants and third party intermediaries with time to adapt to the changes in policy, requirements, and programming updates that would need to occur in technological systems. Therefore, we believe it is appropriate to delay the implementation and availability of the proposed MVPs, described in Appendix 3: MVP Inventory of this proposed rule until the 2023 performance period/2025 MIPS payment year, of the MIPS program. We propose at § 414.1365(a)(1), that for the 2023 MIPS performance period/2025 MIPS payment year, and future years, we use MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking to assess performance for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

In addition to proposing a timeline in which MVPs would be first available, we also believe it is important to be transparent with the agency's current vision and request public comment on the timing of how long MVP reporting should be voluntary, the transition to mandatory MVP reporting, and the timing for when we should sunset traditional MIPS.

While we have heard from stakeholders their request for us to maintain both reporting methods, traditional MIPS and MIPS Value Pathways, we believe it is not a feasible option long term, because of the operational burden, complexity, and costs associated with simultaneously maintaining both versions of the program.

We have also heard from stakeholders (through the MVP Town Hall and from Health Affairs [195]) the importance in continuing this shift to value through MVPs, and doing so by providing as much transparency as possible. We agree, and believe that providing transparency with our thinking (in terms of a transition timeline) and seeking public comment will serve to provide stakeholders with important information to make informed decisions about their eventual transition to MVP reporting. We believe it is critical to establish a timeline for the awareness of all stakeholders (such as MVP participants, third party intermediaries, and health systems) so they can plan their work accordingly to coincide with this timeline.

As such, we outline a timeline in which MVP implementation could occur. As stated above, we are proposing at § 414.1365(a) that the first year MVP reporting be available is the CY 2023 MIPS performance period/2025 MIPS payment year. Based on the discussion above, we are proposing for the CY 2023 MIPS performance period/2025 MIPS payment year, MVP reporting is voluntary. We request comments on this proposal.

Through the remainder of the timeline outlined in Table 31, we seek to lay out our thinking for the future of the MIPS program, for purposes of transparency, and to request public comment. We believe moving forward with voluntary MVP reporting in the initial years would provide MVP participants sufficient time to prepare for mandatory MVP reporting. Therefore, as outlined below, we are considering MVP reporting would be voluntary for the CY 2023 through the CY 2027 MIPS performance periods/2025 through the 2029 MIPS payment years. Furthermore, we plan for potential future mandatory MVP reporting to coincide with the sunset of traditional MIPS.

TABLE 31: MVP Implementation Timeline

MVP Implementation Timeline	
Proposal:	
CY 2023 MIPS Performance Period	As proposed at § 414.1365 (a), an initial set of MVPs are available for reporting; MVP reporting is *voluntary*.
For Future Consideration:	
CY 2024- CY 2027 MIPS Performance Periods	The existing MVP portfolio would be gradually updated to include newly developed MVPs that are available for reporting. MVP reporting is *voluntary*.
End of CY 2027 MIPS Performance Period and Corresponding Data Submission Period	Considered sunset of traditional MIPS.
CY 2028 MIPS Performance Period, and Future Years	Considered *mandatory* MVP reporting.

As previously described, maintaining both traditional MIPS and MVPs is not a feasible long-term approach for the agency. As such, we are thinking of sunsetting traditional MIPS by the end of the CY 2027 performance period/2029 MIPS payment year. We would like to note that we are not proposing the timeframe in which MVP reporting would no longer be voluntary (by the end of the CY 2027 performance period/2029 MIPS payment year), and the future sunset of traditional MIPS at this time; any proposal to sunset traditional MIPS would be made in future rulemaking. Our discussion of the MVP implementation timeline is an effort to be transparent with our long-term vision of the MIPS program.

We request public comments on this incremental timeline to transition to mandatory MVP reporting, including the timing of the sunset of traditional MIPS. Specifically, are there concerns with this timeline? Is there an alternative timeline we should consider and why? In addition, what factors should CMS monitor to determine stakeholders readiness to sunset traditional MIPS and transition to MVPs? We understand that some clinicians who participate in MIPS practice in highly specialized clinical

[195] ''Medicare Should Transform MIPS, Not Scrap It,'' Health Affairs Blog, March 2, 2021. DOI: 10.1377/hblog20210226.949893.

areas and subspecialties, where they may believe there is not an MVP applicable to their highly specialized practice. Therefore, we also request comment on what should happen in instances where highly specialized clinicians cannot identify an applicable and relevant MVP.

We request public comments on this approach.

(ii) Subgroup Implementation Timeline

In the CY 2021 PFS final rule (85 FR 84845), we signaled our intent to implement subgroup reporting by finalizing modifications to the MVP guiding principles. We refer readers to section IV.A.3.b.(3) of this proposed rule for detailed discussion of subgroup proposals; and to section IV.A.3.b.(3)(c) of this proposed rule and § 414.1305 for the definitions of groups, multispecialty groups, single specialty groups, and subgroups.

From our understanding, groups may be made up of a single specialty or of multiple specialties. We do not believe that single specialty groups, should be required to form subgroups in order to report MVPs. In this scenario, we believe that a single specialty group would be able to report on the same set of relevant and applicable measures for all clinicians within the group, and would be able to ascertain results that may lead to improvements in the patient care provided. Therefore, for now, we do not anticipate the need to require single specialty groups to form subgroups in order to report an MVP.

The intent of the subgroup reporting proposals is to move away from large multispecialty groups reporting on the same set of measures, which may not be relevant or meaningful to all specialists that participate within a multispecialty group. In addition, we have heard from stakeholders over the past few years that large multispecialty groups tend to submit data that is not necessarily representative of all the clinicians that make up that group. For example, a group from a large hospital system, may include various specialties such as primary care, oncology, surgery, anesthesia, and radiology that submit data to CMS on primary care quality measures. We are concerned that these type of group submissions do not accurately reflect the performance of all clinicians within the group, and does not provide all clinicians with results that leads to quality improvement in the care provided. In addition, we do not believe that the other specialties within the group can make data-driven improvements in the quality of patient care provided, when only primary care measure data is submitted to CMS; and the results of that data submission is only relevant to the primary care clinicians. From the patient and caregiver perspective, only receiving information on primary care measures when searching for a specialist is not helpful. Data submitted at the subgroup level would provide increased data granularity that patients and caregivers could use in making data-driven decisions regarding the involvement of specialists in their care. In addition, we believe that transitioning multispecialty groups to subgroup reporting will address some of the inherent gaming risks that are apparent when we have multi-specialty groups report on measures that are not necessarily representative of the care provided by all clinicians within the group, where clinicians in a group may rely on the performance of other clinicians (of a different specialty) within the group to meet quality reporting requirements. We anticipate that multispecialty groups would need some time to familiarize and prepare themselves for subgroup reporting.

We refer readers to section IV.A.3.b.(2)(c)(i) of this proposed rule, where we discuss the proposed MVP Participant definition. Through the proposed MVP Participant definition, multispecialty groups and single specialty groups may report as groups or choose to form subgroups to report MVPs for the CY 2023 and CY 2024 performance period/2025 and 2026 MIPS payment year. We believe that the delayed implementation of subgroups for the CY 2023 MIPS performance period/2025 MIPS payment year provides third party intermediaries with sufficient time to adapt to the changes in policy, requirements, and programming updates that would need to occur in technological systems to support subgroup reporting. We encourage the early adoption of subgroup reporting to allow groups to gain experience with the future state of the program.

In addition, beginning with the CY 2025 MIPS performance period/2027 MIPS payment year, we propose through the MVP Participant definition to no longer allow multispecialty groups to report MVPs. This would mean that if a multispecialty group would like to report MVPs, beginning with the CY 2025 MIPS performance period/2027 MIPS payment year, they could only do so if they form subgroups. We believe this 2-year span of time would give multispecialty groups time to familiarize themselves and prepare for subgroup reporting. We strongly encourage multispecialty groups to monitor the implementation of MVPs to determine when to adopt subgroup reporting and transition to MVPs prior to the CY 2025 MIPS performance period/2027 MIPS payment year. We encourage groups to adopt MVP and subgroup reporting as early as possible to provide some time to work through any inadvertent operational issues they may encounter as MVP participants prepare for the future of the MIPS program. While we understand that groups may choose between MVP reporting and continuing to participate through traditional MIPS, we highly encourage groups to submit via subgroups if applicable in the first few years of MVP reporting. We believe early adoption of MVPs and subgroup reporting is important for stakeholders, as this would allow clinicians to acclimate to MVP reporting in the event we sunset traditional MIPS in the future.

We understand that some clinicians practice utilizing a team-based care approach, through a multispecialty group. We believe that MVP reporting can continue to foster the utilization of team-based care through subgroup reporting. As such, we describe in section IV.A.3.b.(4)(b)(i)(A) of this proposed rule, that MVPs may be developed to reflect the team-based care approach used during an episode of care. A proposed timeline to implement subgroup reporting is outlined in Table 32.

TABLE 32: Subgroup Implementation Timeline for MVP Reporting

Subgroup Implementation Timeline*	
CY 2023- CY 2024 MIPS Performance Period/ 2025 and 2026 MIPS payment years	Groups may voluntarily form subgroups to report MVPs.
CY 2025 MIPS Performance Period/2027 MIPS payment year, and Future Years	Multispecialty groups would be required to form subgroups in order to report MVPs.

** As discussed above, we are not proposing that MVP reporting is mandatory. We have outlined and requested public comment on our future timeline.*

As we continue to expand the portfolio of MVPs available over the next few years, MIPS eligible clinicians, groups, and APM entities that do not have a relevant MVP for reporting could continue to report through traditional MIPS. We plan to time the sunset of traditional MIPS with the implementation of an appropriate portfolio of MVPs that are relevant to specialists that participate in the MIPS program. Until that time, there may be instances where some clinicians in a multispecialty group may have a relevant MVP available for reporting, while other clinicians within that same multispecialty group may not. In this scenario, the clinicians within the multispecialty group that have an MVP available may form a subgroup to report the MVP, while the group continues to report traditional MIPS. We refer readers to section IV.A.3.b.(3) of this proposed rule for additional discussion of subgroup proposals.

We believe there is a need for multispecialty groups to transition to subgroup reporting in order to align with the goals of MVP reporting. That is, to provide more direct attribution of quality measure data and results to all clinicians that participate in the program rather than relying on quality reporting results that can only be attributed to a few clinicians within the group. This direct attribution would lead to more valuable, meaningful, and actionable results that contribute to patient care and improvement. We refer readers to sections IV.A.3.b.(3) and IV.A.3.b.(4)(d) of this proposed rule for a detailed discussion of subgroup proposals and MVP reporting requirement proposals.

(e) Subgroups Reporting the APM Performance Pathway (APP)

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the availability of the APM Performance Pathway beginning with the CY 2021 performance period. Specifically, we finalized that individual MIPS eligible clinicians who are participants in MIPS APMs may report through the APP at the individual level (85 FR 84860). Furthermore, we finalized that groups and APM Entities may report through the APP on behalf of constituent MIPS eligible clinicians (85 FR 84860). Because we already identify the MIPS eligible clinicians who are MIPS APM participants based on Participation Lists for each APM, it is unnecessary to require MIPS APM participants to register as subgroups for purposes of reporting the APP. We use Participation Lists to identify each individual APM participant for purposes of MIPS APM participation, as well as application of the Improvement Activities credit for APM participants; beginning with performance year 2023, we will use Participation Lists to identify the MIPS eligible clinicians within a group TIN that should be included in the subgroup of APM participants for purposes of reporting the APP.

(f) Catalyst for Reporting MVPs

(i) Background

Through the MIPS Value Pathways framework, finalized in the CY 2020 PFS final rule (84 FR 62946 through 62949), stakeholders provided feedback, specifically questioning what incentives would MVP Participants have to report on MVPs, when they have the choice to report traditional MIPS instead. We have heard these questions raised through multiple methods, including public comment through rulemaking, meetings, and the MVP Town Hall that was held in January 2021. Through this rule, we have proposed MVP policies that we believe act as catalysts to encourage MVP Participants to transition to MVP reporting. This includes reduced reporting requirements, as described in section IV.A.3.b.(4)(d) of this proposed rule, allowing MVP Participants to report on a smaller, more cohesive subset of measures and activities that are relevant to a given clinical topic, condition, procedure, or episode of care. In addition, as described in section IV.A.3.b.(5)(d) of this proposed rule, we propose to provide MVP Participants who report on MVPs with enhanced performance feedback that allows for meaningful comparison to similar clinicians and provides more useful information to make improvements in the care provided.

Additionally, we understand that clinicians have other requirements that must be met to maintain their licensure and as appropriate board certification status. In many instances, clinicians must comply with Continuing Medical Education (CME) requirements and/or Maintenance of Certification (MOC) requirements. We believe that any alignment between what clinicians must do to maintain their licensures/board certifications and reporting MVPs would be beneficial by reducing burden in terms of the various requirements clinicians must comply with. Therefore, in some cases, it seems possible that offering CME credit or credit towards MOC could be connected with MVPs. We encourage accrediting organizations such as specialty societies, to work with MVP submitters and consider whether CME credit or credit towards MOC could be offered for reporting MVPs. We believe by allowing clinicians to receive CME credit for MVP reporting, there is potential for there to be a reduction in the administrative burden clinicians face when trying to balance meeting CMS program requirements with the requirements of medical licensing or certification.

Proposing incentives for clinicians to report on MVPs in lieu of traditional MIPS may encourage early adoption of MVPs and allows those clinicians to gain experience with the future state of the program. We believe that creating incentives to report MVPs may help MVP participants familiarize themselves with MVP reporting requirements, particularly in cases where clinicians identify an available MVP as relevant to their practice.

(ii) Public Reporting of MVP Data

We have heard from stakeholders who expressed hesitancy to partake in the initial transition to MVP reporting citing concerns with what results may be publicly reported. We refer readers to

section IV.A.3.i. of this proposed rule for discussion of public reporting proposals related to MVP data and subgroup reporting.

(3) Subgroup Composition

(a) Overview

In the CY 2021 PFS final rule, we finalized updates to MVP guiding principles (85 FR 84844 through 84849), including the addition of subgroup reporting to enhance comparative performance data, and MVP development criteria and process (85 FR 84845 through 84849) that guide MVP implementation. Through this proposed rule, we are proposing to establish subgroup reporting as an option for MVP Participants and for those individuals and entities who choose to report the APP. In this section, we propose: (1) Definitions for subgroup reporting, single specialty group, multispecialty group, and special status designation; (2) subgroup eligibility requirements; and (3) application of low-volume threshold and special status designations for subgroups. In this section, we also have a request for information on the future direction of subgroup reporting. Additionally, we refer readers to section IV.A.3.b.(4) of this proposed rule, where we detail our proposals on: (1) Subgroup reporting requirements; (2) subgroup election process; and (3) subgroup identification. In section IV.A.3.b.(5) of this proposed rule, we detail our proposals on subgroup scoring.

(b) Background

Section 1848(q)(1)(D)(i) of the Act requires that the Secretary establish and apply a process that includes features of the provisions of section 1848(m)(3)(C) of the Act for group practice reporting for the quality performance category and provides that the Secretary may establish such a process for the other MIPS performance categories. At § 414.1305, a group is defined as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. In the CY 2021 PFS final rule, we finalized updates to MVP guiding principles (85 FR 84844 through 84849), including the addition of subgroup reporting to enhance comparative performance data, and MVP development criteria and process (85 FR 84849 through 84853) that guide MVP implementation. In section IV.A.3.b.(2)(d)(ii) of this proposed rule, we propose to allow voluntary MVP reporting beginning with the CY 2023 MIPS performance period/2025 MIPS payment year and are considering mandatory MVP reporting to coincide with the sunset of traditional MIPS beginning with the CY 2028 MIPS performance period/2030 MIPS payment year. We believe one important element of transitioning to MVPs is allowing clinicians the ability to report and be assessed on measures and activities which are meaningful to their practice. Currently, within the MIPS program, we offer clinicians many opportunities to participate, including as an individual and as a group; we have found most clinicians choose the group reporting option. We anticipate some groups may consist of clinicians who all practice under a single-specialty or clinical focus and are able to successfully select an MVP whose measures and activities are applicable and meaningful to all or a significant majority of their patients or practice. On the other hand, some groups encompass 20 or more different specialties, contain many clinicians, and often provide an array of services that may not be captured in a single set of measures or in a single MVP. For instance, we estimated in the CY 2021 PFS final rule RIA that among the 863,627 clinicians who submitted data, 510,057 were in practices with more than 100 clinicians (85 FR 85019). This represents 59 percent of the total MIPS eligible clinician population estimated for the CY 2023 payment year using 2019 submissions data (85 FR 85019).

In the 2017 Quality Payment Program final rule (81 FR 77058), commenters had noted interest in CMS providing additional flexibility to allow clinicians to submit information that would represent reporting for some portion, but not the entirety, of a group or TIN. In the CY 2018 Quality Payment Program final rule (82 FR 53593), we stated that in future rulemaking we intend to explore the feasibility of establishing group-related policies which would permit participation in MIPS at a subgroup level and create such functionality through a new identifier. Prior to the introduction of MVPs, in the CY 2019 PFS proposed rule (83 FR 35891), we again acknowledged the overarching themes from stakeholders that we should make an option available to groups which would allow a portion of a group to report as a separate subgroup on measures and activities which are more applicable to the subgroup and be assessed and scored accordingly based on the performance of the subgroup. We solicited comment on specific options and questions for implementation of subgroup level reporting in future years. However, as we noted in the CY 2019 PFS final rule (83 FR 59742), because there are numerous operational challenges with implementing a subgroup option, we did not propose any changes to our established reporting policies regarding the use of a subgroup identifier.

In the CY 2020 PFS proposed rule (84 FR 40740 through 40741), we sought comment on MVP policies for multispecialty practices. Overall, we heard from commenters that subgroup reporting should be offered as an additional reporting option where subgroup reporting would provide more specific information for patients and clinicians rather than having multispecialty groups report on multiple MVPs at the group level. We also sought comment in the CY 2020 PFS proposed rule (84 FR 40740 through 40741) on whether we should use an approach in which groups submitted data on multiple MVPs reflecting their diverse specialties as an alternative to subgroup reporting to more comprehensively capture the range of items and services furnished by a group practice. Several commenters voiced concerns related to tradeoffs between the burden of reporting multiple MVPs and having more comprehensive performance data. Many commenters urged CMS to allow for subgroups and did not see reporting on multiple MVPs by the entire group as an alternative to subgroup reporting. Some commenters recommended allowing subgroup reporting in lieu of MVPs, while others recommended subgroup reporting for either the traditional MIPS program rules or for MVPs. A few commenters recommended steps we could take to identify subgroups, including creating a subgroup identifier and allowing the formation of subgroups through an election process at the Quality Payment Program website (*qpp.cms.gov*) that would function similarly to CMS Web Interface or CAHPS for MIPS registration. A few commenters suggested that allowing subgroup reporting may be necessary to implement MVPs and help groups, particularly multispecialty practices, meet data completeness criteria.

Additionally, in response to our request for comment on whether we could use the MVP approach as an alternative to subgroup reporting to more comprehensively capture the range of items and services furnished by a group practice, we heard concerns that subgroup reporting may deter group practices from utilizing a team approach to patient care, may make departments more competitive, may not improve care for patients, and may increase errors,

costs, stress, and administrative burdens to implementation across various departments. In considering these concerns, we have continued to work towards meaningful subgroup reporting that balances the hurdles of a new reporting option with the benefits of more comprehensive and granular data available for patients and clinicians.

We held the MVP Town Hall on January 7, 2021 (85 FR 74729) and publicly shared the MVP Town Hall Preparation Guide (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1233/MVP%20Town%20Hall%20Preparation%20Guide.pdf*) to aid MVP Town Hall participants in understanding the direction we may take with MVPs and subgroups. We sought public comment on the MVP Town Hall topics and the approaches outlined in the MVP Town Hall Preparation Guide (recording available at *https://www.youtube.com/watch?v=7CjQeuD3eFE&feature=youtu.be*). Overall, several commenters supported the option of voluntary subgroup reporting and recognized the value for patient care and research. Several commenters suggested CMS to allow sufficient time for CMS and stakeholders to make software changes (that include coding, development, testing, production, training, and education tasks) to support subgroup reporting, ultimately recommending CMS to slow down implementation. Additionally, we have solicited comment from stakeholders beginning in the CY 2018 PFS proposed rule (82 FR 30027) through the MVP Town Hall (85 FR 74729) on the ways in which participation in MIPS at the subgroup level could be established. In considering stakeholder feedback—in conjunction with the introduction of MVPs, technical innovations, and working through operational issues within CMS—we are ready to propose subgroup reporting. We acknowledge some clinicians in multispecialty groups are currently not able to report as a team for the measures that are meaningful to them because the group reports on behalf of all clinicians within the practice. Even with the introduction of MVP reporting, we anticipate this problem could persist if subgroup reporting is not offered as a reporting option for MIPS. Therefore, subgroup reporting would provide an avenue for clinical teams within a larger group to be able to submit MVPs that are clinically relevant to them. It would also be a first step in allowing for more granular clinician information to be made available to patients.

We thank commenters for their feedback. After considering the feedback, in section IV.A.3.b.(2)(d)(ii) of this rule, we propose voluntary subgroup reporting in MIPS beginning with the CY 2023 MIPS performance period/2025 MIPS payment year for MIPS eligible clinicians and groups who participate in MIPS through MVP reporting. As discussed in section IV.A.3.b.(3)(d)(iv)(B) of this proposed rule, APM Entities can report to MIPS through MVPs but may not break out into subgroups. As discussed in section IV.A.3.b.(2)(d)(ii) of this proposed rule, we are proposing that beginning in the CY 2025 MIPS performance period/2027 MIPS payment year, multispecialty groups would be required to form subgroups in order to report MVPs.

(c) Definitions of a Single Specialty Group, Multispecialty Group, Subgroup, and Special Status

A group is currently defined at § 414.1305 as a single TIN with two or more eligible clinicians (including at least one MIPS eligible clinician), as identified by their individual NPI, who have reassigned their billing rights to the TIN. As discussed in section IV.A.3.b.(3)(d) of this proposed rule, we are proposing to use certain characteristics of the group to determine eligibility and special status of the clinicians in the subgroup. To provide clarity, we are proposing definitions for single specialty groups, multispecialty groups, subgroups, and special status.

(i) Proposed Single Specialty and Multispecialty Groups Definitions

We propose to add to § 414.1305 to include that a single specialty group is a group as defined at § 414.1305 that consists of one specialty type as identified by eligible clinicians in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) (*https://pecos.cms.hhs.gov/*). We believe that using clinician specialty information from PECOS would allow us to align data sources and create greater consistency within the program given that PECOS specialty information is publicly reported on Care Tools.[196] We refer readers to our comment solicitation in section IV.A.3.b.(3)(h)(iv) of this proposed rule, where we request information on the threshold that subgroups would have to meet in order to be defined as a single specialty (such as having at least 75 percent of clinicians sharing the same specialty in a subgroup).

We also propose to add to § 414.1305 to include that a multispecialty group is a group as defined at § 414.1305 that consists of two or more specialty types as identified by eligible clinicians in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). We refer readers to our comment solicitation in section IV.A.3.b.(3)(h)(iv) of this proposed rule, where we request information on setting the threshold that subgroups would have to meet in order to be defined as a multispecialty group. Beginning in the CY 2025 MIPS performance period/CY 2027 MIPS payment year and discussed in section IV.A.3.b.(2)(d)(ii) of this proposed rule, multispecialty groups would be required to form subgroups in order to report MVPs.

Additionally, we recognize that individual eligible clinicians may practice or be a part of multiple specialties as a part of their scope of practice and that eligible clinicians may have more than one specialty designation in PECOS. These clinicians could participate in multiple subgroups and report on multiple MVPs or clinicians could join a subgroup that is most applicable to their scope of practice and report on one MVP. We anticipate that at a future time when subgroup reporting is mandatory, that there will need to be criteria to determine which specialty is a primary specialty of clinicians. At this time, we do not have limitations on which specialty will be considered the primary specialty. However, we refer readers to section IV.A.3.b.(3)(h)(iv) of this proposed rule, where we request information on the identification of a primary specialty in scenarios where an eligible clinician may have more than one.

We request public comment on these proposals.

(ii) Proposed Subgroup Definition

We propose to define a subgroup at § 414.1305 as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. Groups would identify their affiliated subgroups, and those subgroups would submit data on the MVPs which are clinically meaningful to MIPS eligible clinicians within a subgroup or their patients. We propose at § 414.1318(b) to state that except as provided under § 414.1317(b), each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment. Additionally, we propose to amend § 414.1310(e)(1) to state that except as provided under §§ 414.1315(a)(2), 414.1317(b),

[196] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/About-Physician-Compare-An-Overview.*

414.1318(b), and 414.1370(f)(2) each MIPS eligible clinician in the group receives a final score based on the group's combined performance assessment. With the inclusion of the exception provided under § 414.1318(b), this would allow for an exception for subgroups to receive a final score based on the subgroup's combined performance.

We note that in these proposed additions to and amendments of the regulation text, we refer to the final score instead of the MIPS payment adjustment factor (or additional MIPS payment adjustment factor) because we believe this phrasing is more precise. It is possible that more than one final score could be associated with a TIN/NPI for a performance period, and in those situations, we apply a final score hierarchy for purposes of determining the MIPS payment adjustment for that TIN/NPI (see, for example, the discussion in the CY 2021 PFS final rule (85 FR 84917 through 84919)). We believe allowing and, beginning with the CY 2025 MIPS performance period/CY 2027 MIPS payment year, requiring subgroup reporting for MVPs would offer clinicians the opportunity to participate in MIPS more meaningfully and would allow patients to have more granular and meaningful information when selecting an eligible clinician.

Measuring performance at the subgroup level would still allow for groups to practice team-based care, with groups having the ability to self-define which clinicians participate in which subgroups. Team-based health care is defined by the National Academy of Medicine as ''the provision of health services to individuals, families, and/or their communities by at least two health providers who work collaboratively with patients and their caregivers—to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality care.'' [197] As discussed in section IV.A.3.b.(3)(d)(iii) of this proposed rule, we request comments on how to establish criteria around the composition of subgroups; criteria may include clinical relevance, scope of care, and patient population.

As discussed in section IV.A.3.b.(2)(d)(ii) of this proposed rule, MIPS eligible clinicians in groups who do not have an MVP available and applicable to their practice would participate in MIPS through group reporting or as an individual. If their group reports through traditional MIPS or an MVP, the clinicians could receive their group's score, if their group submits data. If the group chooses not to report, a MIPS eligible clinician can report as an individual and receive their individual score. While subgroup reporting of MVPs would be voluntary through the CY 2024 MIPS performance period/CY 2026 MIPS payment year, groups will continue to report to MIPS for the eligible clinicians (as identified by NPI) under their TIN, including clinicians reporting through subgroups, which is discussed in section IV.A.3.b.(2)(d)(i) of this proposed rule.

We request public comment on this proposal.

(iii) Proposed Special Status Definition

In the CY 2018 Quality Payment Program final rule, we finalized definitions for special status determinations for ambulatory surgical center (ASC)-based MIPS eligible clinicians, facility-based MIPS eligible clinicians, Health Professional Shortage Areas (HPSA), hospital-based MIPS eligible clinicians, non-patient facing MIPS eligible clinicians, rural area, or small practice status and codified at § 414.1305 definitions for each (82 FR 53479 through 53586). We often refer informally to these as ''special status''; however, we have not previously defined what ''special status'' means. Therefore, we propose to add to § 414.1305 and define that special status means that a MIPS eligible clinician: (1) Meets the definition of an ASC-based MIPS eligible clinician, facility-based MIPS eligible clinician, hospital-based MIPS eligible clinician, non-patient facing MIPS eligible clinician, or is in a small practice; or (2) is located in an HSPA or rural area. We believe that defining special status will help clinicians better understand the application of subgroup policies.

We request public comment on this proposal.

(d) Subgroup Eligibility

As described in section IV.A.3.b.(3)(c)(ii) of this proposed rule, we are proposing voluntary subgroup reporting for clinicians beginning with the CY 2023 MIPS performance period/CY 2025 MIPS payment year and to define subgroup as a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI.

During the MVP Town Hall held in January 2021 (85 FR 74729 to 74730), stakeholders expressed concern about creating separate eligibility criteria and associated policies which would lead to confusion and additional burden for clinicians in subgroups and associated groups. These stakeholders recommended that eligibility for subgroup reporting be based on group eligibility. Additionally, during the initial years of MVP implementation, we recognize that there may be an inadequate number of MVPs available for clinicians to participate as subgroups. Therefore, in this proposed rule, we are proposing: (1) Application of a low-volume threshold; (2) application of special status designation; and (3) subgroup inclusions and exclusions. Additionally, we seek comment on subgroup composition and limitations.

(i) Proposed Application of Low-Volume Threshold

We considered whether a low-volume threshold for clinicians participating in subgroup reporting should be calculated at the group or subgroup level. In consideration of stakeholder feedback and to minimize changes in eligibility determination for clinicians, we believe it would be optimal to determine the low-volume threshold for clinicians participating in a subgroup at the group level. As we implement subgroup reporting and as clinicians and groups familiarize themselves with this new participation option, we believe we should limit the complexity of the program to the extent that is feasible.

At § 414.1305, one of the ways we determine MIPS eligibility is by defining how the low-volume threshold is applied to individual clinicians and groups. We determine eligibility for MIPS during two different eligibility periods, which include an assessment of: (1) Those who have allowed charges for covered professional services less than or equal to $90,000; (2) those who provide covered professional services to 200 or fewer Part B-enrolled individuals; and (3) those who provide 200 or fewer covered professional services to Part B-enrolled individuals (83 FR 59735) provided by the clinician and group during that time-period. Therefore, we propose at § 414.1318(a)(1) that except as provided under § 414.1318(a)(2), for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for subgroups are determined at the group level as provided under §§ 414.1305 and 414.1310.

We request public comment on this proposal. As MVPs continue to evolve, we anticipate increased opportunities for clinician participation in subgroups,

[197] Mitchell, P., M. Wynia, R. Golden, B. McNellis, S. Okun, C.E. Webb, V. Rohrbach, and I. Von Kohorn. 2012. Core principles & values of effective team-based health care. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, D.C. *https://doi.org/10.31478/201210c.*

and we also request feedback from stakeholders if we should reevaluate, in the future, MIPS eligibility for clinician participation in subgroups at the subgroup level.

(ii) Proposed Application of Special Status Designation

Groups in MIPS could have their data submission requirements and scoring affected by special statuses outside of their underlying eligibility for MIPS. Each of these special statuses, described in section IV.A.3.b.(3)(c)(iii) of this proposed rule, are determined at the time of eligibility determinations.

We propose at § 414.1318(a)(1) for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status, as defined at § 414.1305, for subgroups is determined at the group level as provided under § 414.1310. We believe it is necessary to explain how special status determinations would work in the context of subgroup reporting. For example, a large, multispecialty group may include subgroups of clinicians that meet the requirements for small practice status, or non-patient facing status, or facility-based status. While we are certain some existing groups could have subgroups that could be eligible at the subgroup level for special status designation as described in section IV.A.3.b.(3)(c)(iii) of this proposed rule, we do not believe that this determination should be made at the subgroup level at this time. We want to deter construction of subgroups that would inappropriately create special status exemptions, such as subgroups of 15 or fewer clinicians in a large group. Overall, we believe this should help limit the complexity of the program as we implement this new participation option.

Additionally, at this time, we are not planning to establish limits on the number of subgroups that a clinician can be part of. For example, a primary care clinician who is part of a multispecialty group may choose to participate in a subgroup. This subgroup may choose to report through two MVPs because they believe both were relevant to the scope of care provided by the clinicians in their subgroup and under this example, the subgroup would be allowed to report and be assessed on both MVPs if they choose to do so. While we acknowledge the potential for clinicians to participate in multiple subgroups for reporting MVPs, we also recognize the burden for groups to submit data for an unlimited number of subgroups for each clinician, but we anticipate this will be an uncommon scenario. For instance, we do not anticipate that a group of 20 specialties would want to form 100 subgroups and be assessed on all the applicable MVPs. We believe clinician participation in subgroup reporting will be based on the scope of clinical care provided or a relevant specialty type and clinicians would not use subgroup reporting to game the MIPS program. We will monitor the ways in which clinicians form subgroups and will revisit this issue in future rulemaking if we discover that clinician participation in multiple subgroups is not what we intended.

We request public comments on this proposal.

(iii) Subgroup Composition Limitations

We are not proposing to require any criteria for the composition of subgroups at this time; however, as discussed in section IV.A.3.b.(3)(h) of this proposed rule, we are seeking comment on criteria that we could consider in the future, such as in the CY 2023 PFS rulemaking cycle. In developing the voluntary subgroup reporting proposal, we also considered whether we should limit the opportunity for clinicians to participate as a subgroup based on certain characteristics for the first year of voluntary subgroup reporting and in the future under mandatory subgroup reporting. As we have noted in this section of the rule, many stakeholders requested that we create an opportunity to participate via subgroups and suggested that participation in subgroups would allow clinicians across different specialties within a practice to report.

We considered whether we should limit the composition of a subgroup to clinicians of the same specialty or a related specialty. We are also aware clinicians providing patient care as part of a clinical team may practice in different locations under the same group (TIN) and may be interested in reporting through different subgroups. These clinicians may practice in specific clinical settings, such as dialysis centers or urgent care settings, and may use different third-party intermediaries, such as different EHR vendors or qualified registries. Alternatively, we considered if we should establish limits on the size of a subgroup, such as setting minimum and maximum thresholds for the number of clinicians that could participate as a subgroup. Similarly, we considered establishing a threshold where 75 percent of the eligible clinicians in a group or subgroup would have to be of the same specialty or a related specialty to report a given MVP, and thus form a subgroup. We also considered if we should establish criteria based on the number of clinicians practicing in a group, specialty mix assessed through analyzing previous billing patterns within a group, practice location, type of clinical setting, patient population, or scope of care provided. Additionally, we also considered establishing restrictions on the type of clinicians who can report a given MVP. In considering these potential restrictions, we are concerned we would be unable to anticipate the different methods by which groups may wish to utilize subgroup reporting without seeking public comment on the best approach.

As MVPs evolve and subgroup reporting becomes mandatory in the future, we plan to explore the options for establishing criteria for composition of subgroups. We recognize that MVPs will continue to be developed by the time subgroup reporting is mandatory for MVP reporting by multispecialty groups and that there will be clinicians in multispecialty groups who do not have an available MVP, and thus, would be unable to form subgroups. We believe it is valuable for multispecialty group practices to gain experience with subgroup reporting while MVPs continue to be developed. We also note that as described below in this section, APM Entities cannot be broken down into subgroups because APM Entities are often composed of multiple TINs. We refer readers to section IV.A.3.b.(4)(d) of this proposed rule for additional details on MVP and subgroup reporting requirements for APM Entities.

Therefore, we request comment from stakeholders on the options for multispecialty groups to participate as subgroups for reporting MVPs for the first year of voluntary subgroup reporting, beginning in the CY 2023 MIPS performance period/2025 MIPS payment year. We also request feedback from stakeholders on whether restrictions should be applied in the future for the composition of subgroups and any associated criteria that need to be established without needlessly limiting flexibility for clinicians involved in team-based care. We request public comment on the criteria which should be used to define what types of groups are required to report more than one MVP.

(iv) Proposed Subgroup Inclusions and Exclusions

(aa) Background

We recognize MIPS eligible clinicians participating in subgroups may be part of a group that has a portion of its

clinicians participating in MIPS as part of a virtual group, MIPS APM, or clinicians that do not attain QP or Partial QP status in an Advanced APM. Eligible clinicians may participate in MIPS if they meet at least one of the low-volume threshold criteria and choose to opt-in to MIPS reporting (83 FR 59740). Eligible clinicians (as defined at § 414.1305) who are not MIPS eligible, have the option to voluntarily report on applicable measures and activities for MIPS and these clinicians will not be subject to MIPS payment adjustment (81 FR 77041). Additionally, Partial QPs in Advanced APMs will have the option to elect whether or not to report under MIPS, which determines whether or not they will be subject to MIPS payment adjustments (81 FR 77062). We believe eligible clinicians in MIPS APMs, clinicians that do not attain QP or Partial QP status in Advanced APMs, or who are opt-in eligible may desire to participate as subgroups for reporting MVPs and may meet the proposed criteria for definition of a subgroup as described in section IV.A.3.b.(3)(c)(ii) of this proposed rule.

(bb) Proposed Subgroup Eligibility—Participants in MIPS APMs

In the CY 2021 PFS final rule (85 FR 84860), we finalized a policy to allow groups and APM Entities to report through the APP on behalf of their constituent MIPS eligible clinicians. We believe that an APM Entity should not be eligible to form subgroups for reporting MVPs or the APP because APM Entities are often composed of multiple TINs and may use multiple EHR systems. We believe that the definition of a subgroup consisting of one TIN, as proposed in section IV.A.3.b.(3)(c)(ii) of this rule, would not include APM Entities comprised of more than one TIN, which would result in exclusion of APM Entities from forming subgroups for reporting MVPs or the APP. We anticipate that eligible clinicians in APM Entities comprised of multiple TINs could choose to form subgroups through their affiliated TIN. We refer readers to section IV.A.3.b.(4)(d)(vi)(B) of this rule where we seek comment on whether there are strategies that CMS should consider to allow the formation of subgroups for clinicians in APM Entities comprised of multiple billing TINs. We also note that, in cases where an APM Entity is itself comprised of a single TIN, the single TIN could form subgroups under the TIN, rather than under the APM Entity ID.

(cc) Proposed Subgroup Exclusions—Opt-In Eligible Clinicians and Voluntary Participants

Based on historical data, a significantly low number of clinicians have utilized the following participation options in MIPS: Virtual groups; opt-in eligible clinicians; and voluntary reporters. For example, if the number of opt-in eligible clinicians remains the same as estimated in the CY 2021 PFS final rule (85 FR 85015), we anticipate that an estimated 0.3 percent of the total number of MIPS eligible clinicians would fit into this category. We believe that there are several operational considerations, such as implementation burden for stakeholders and CMS, value of subgroup reporting for these clinicians versus burden, scoring policies, etc. that must be addressed prior to allowing clinicians in these categories to participate as subgroups for reporting MVPs. Additionally, we believe that the definition of a subgroup consisting of one TIN, as proposed in section IV.A.3.b.(3)(c)(ii) of this rule, would not be applicable for clinicians in a virtual group because a virtual group is a combination of two or more TINs, resulting in exclusion of clinicians in virtual groups from participating as subgroups for reporting MVPs.

Therefore, beginning in the CY 2023 MIPS performance period/2025 MIPS payment year, we are proposing at § 414.1318(a)(2) that an individual clinician or group electing to participate in MIPS as an eligible clinician in accordance with § 414.1310(b)(1)(iii)(A) or § 414.1310(b)(2) is not eligible to participate as a subgroup. As we consider transitioning to MVPs and retiring traditional MIPS, we will revisit subgroup eligibility for opt-in eligible clinicians, voluntary participants and clinicians in virtual groups in future years. We also seek feedback from stakeholders on whether clinicians in these categories should be allowed to form subgroups in future years, and if there are additional criteria that should be established.

We seek public comment on this proposal.

(e) Subgroup Examples

In Appendix 3: MVP Inventory of this proposed rule, we are proposing seven MVPs for implementation in the CY 2023 MIPS performance period/2025 MIPS payment year. We have provided examples below to show how eligible clinicians could choose to participate as subgroups for reporting MVPs if these MVPs are finalized. These examples are not intended to be exhaustive of the eligible clinician types that could participate as subgroup.

Example 1: A group is composed of all anesthesiologists. In this example, all the clinicians in the group have the same primary specialty designation, which is an example for a single-specialty group. We would not anticipate that they would wish to form subgroups but could report the *Patient Safety and Support of Positive Experiences with Anesthesia* MVP as a group.

Example 2: Table 33 illustrates an example of subgroup reporting for a group consisting of anesthesiologists, orthopedic surgeons, and certified registered nurse anesthetists (CRNAs). In this example, the group could form a total of three subgroups. The anesthesiologists and CRNAs could form either one or two subgroups for reporting the proposed *Patient Safety and Support of Positive Experiences with Anesthesia* MVP as described in Table G: Proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year of Appendix 3: MVP Inventory of this proposed rule. We believe the measures and activities included in this MVP would be most applicable to clinicians who provide anesthesia services to patients within the surgical setting, are considered anesthesiologists, or are other qualified anesthesia professionals. For instance, the anesthesiologists and the CRNAs could form separate subgroups for reporting on applicable measures and activities in the MVP. Alternatively, the CRNAs and the anesthesiologists could report on the applicable measures and activities in the MVP as one subgroup if this aligns better with how the subgroup would practice and they all report the same measures and activities. The orthopedic surgeons in the group could then form a separate subgroup to report the applicable measures and activities in the proposed Improving Care for Lower Extremity Joint Repair MVP.

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TABLE 33: Example to Demonstrate Subgroup Participation

Subgroup Example	Measures and Activities in the MVP
Subgroup #1 (Anesthesiologists): *Patient Safety and Support of Positive Experiences with Anesthesia*	***Quality Performance Category*** Q477: Multimodal Pain Management (MIPS CQMs Specifications) AQI48: Patient-Reported Experience with Anesthesia (QCDR) AQI69: Intraoperative Antibiotic Redosing (QCDR) AQI70: Prevention of Arterial Line-related Bloodstream Infections (QCDR) ***Improvement Activities Performance Category*** IA_BE_22: Improved practices that engage patients pre-visit (Medium) IA_BMH_2: Tobacco use (Medium) ***Cost Performance Category*** Medicare Spending Per Beneficiary (MSPB) Clinician
Subgroup #2 (Certified Registered Nurse Anesthetists): *Patient Safety and Support of Positive Experiences with Anesthesia*	***Quality Performance Category*** Q404: Anesthesiology Smoking Abstinence (MIPS CQMs Specifications) Q424: Perioperative Temperature Management (MIPS CQMs Specifications) Q430: Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (MIPS CQMs Specifications) Q463: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (MIPS CQMs Specifications) ***Improvement Activities Performance Category*** IA_BE_22: Improved practices that engage patients pre-visit (Medium) IA_BMH_2: Tobacco use (Medium) ***Cost Performance Category*** Medicare Spending Per Beneficiary (MSPB) Clinician
Subgroup #3 (Orthopedic Surgeons): *Improving Care for Lower Extremity Joint Repair*	***Quality Performance Category*** Q350: Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (MIPS CQMs Specifications) Q351: Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (MIPS CQMs Specifications) Q376: Functional Status Assessment for Total Hip Replacement (eCQM Specifications) Q470: Functional Status After Primary Total Knee Replacement (MIPS CQMs Specification) ***Improvement Activities Performance Category*** (~) IA_CC_9: Implementation of practices/processes for developing regular individual care plans (Medium) IA_CC_13: Practice improvements for bilateral exchange of patient information (Medium) ***Cost Performance Category*** Elective Primary Hip Arthroplasty Knee Arthroplasty
Foundational Layer ***Population Health Measures*** **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) ***Promoting Interoperability (PI) Performance Category*** The subgroup submits the affiliated group's Promoting Interoperability performance category data	

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(f) Third-Party Intermediaries for Subgroup Reporting

As described in section IV.A.3.h.(2)(b) of this proposed rule, we are proposing at § 414.1400(a)(1) for third-party intermediaries to implement MVPs and subgroup reporting options for MIPS eligible clinicians starting with the CY 2023 MIPS performance period/CY 2025 MIPS payment year. Since subgroups will be implemented concurrently with MVPs, we believe that it is important that all third-party intermediaries support subgroup reporting in order for clinicians to meaningfully report MVPs. We refer readers to section IV.A.3.h.(2)(b) of this proposed rule for

additional details on requirements for third-party intermediaries supporting MVPs and subgroups.

(g) Public Reporting of Subgroup Performance Information

As described in section IV.A.3.i.(1) of this proposed rule, we propose to delay public reporting of subgroup performance information by an additional year. Our proposal would result in the public reporting of subgroup performance information beginning with the CY 2024 MIPS performance period/2026 MIPS payment year and each performance period/MIPS payment year thereafter. We refer readers to section IV.A.3.i.(1) of this proposed rule for additional details on the proposed policies related to public reporting of subgroup performance information on the compare tool.

(h) Future Vision of Subgroups

(i) Overview

Given the delay of subgroup and MVP implementation until the CY 2023 MIPS performance period/2025 MIPS payment year, we recognize there are additional policy nuances which need to be worked through during future rulemaking, and we would like to share our vision and request information to help us craft policy solutions. We believe team-based care is an essential element to providing high-quality care to patients and acknowledge some of the subgroup policies may be construed to create competition within groups. It is not our intention to create this competition, rather, we believe as MVPs continue to be created and evolve, this will also include MVPs that are focused on team-based care for some specialties. We share this vision below along with a request for information on the future of subgroup reporting. We welcome feedback and potential alternatives ideas we could consider ensuring the success of subgroup and MVP reporting.

(ii) Vision for Data Granularity

Ultimately, we envision that a future goal of the Quality Payment Program, particularly with MIPS and MVPs, is to ensure there is more granular data available for patients, clinicians, and other stakeholders. We envision an end state where technology will allow for the submission of discrete data elements and allow us to calculate measure performance for clinicians, subgroups, groups, and APM Entities, rather than having measure performance aggregated and calculated at a group or subgroup level prior to reporting. We anticipate more granular data will be available for patients, clinicians, and other stakeholders through a three-pronged approach of mandatory subgroup reporting, broad use of standards-based APIs that leverage the FHIR standard within EHRs (as discussed in section IV.A.1.c.(4)(a) of this proposed rule), and the creation and use of dQMs (as discussed in section IV.A.1.c.(2) of this proposed rule). We believe this would give patients specific and meaningful information which can better inform their choices when selecting a clinician and offer more targeted feedback to clinicians. We request information on the vision for data granularity.

(iii) Sunsetting Traditional MIPS

Given our goals for increasing the level of data that is available to clinicians and patients, we envision a future state where all multispecialty groups would participate in MIPS through subgroup reporting. As additional MVPs are developed and eligible clinicians are given the opportunity to report on MVPs, including reporting via subgroups, we believe that clinicians will have even more meaningful ways to participate in MIPS at a more discrete level. As discussed in section IV.A.3.b.(2)(d) of this proposed rule, we are considering retiring traditional MIPS, where it would no longer be available by the CY 2028 MIPS performance period/2030 MIPS payment year but would make any proposal to do so in a future rulemaking.

If we sunset traditional MIPS beginning in the 2028 MIPS performance period/2030 MIPS payment year, we anticipate that groups, particularly large multispecialty groups, would have had the opportunity to gradually ramp up their reporting on MVPs, gaining a few years of experience reporting on more than one MVP. This allows for clinicians to be assessed on information that is clinically meaningful to their scope of practice and to publicly report that information. At a high-level, if we finalize the proposal as described in section IV.A.3.b.(2)(d)(ii) of this rule, we anticipate that multispecialty groups would report more than 1 MVP beginning in the CY 2025 MIPS performance period/2027 MIPS payment year. We believe that clinicians in multispecialty groups should be assessed on measures and activities that are related to the scope of care that they provide. We believe that in order to meet the goals of MVPs and provide enhanced performance feedback to clinicians and to ensure more granular information is publicly available for patients, multispecialty groups must form subgroups to report additional information. Additionally, we do not believe that there will be an MVP that will be applicable to all types of clinicians within multispecialty groups. We refer readers to section IV.A.3.b.(2)(d) of this rule for additional details on the proposed timeline for MVPs and subgroup implementation.

(iv) Limiting Subgroup Composition to Single-Specialty

We are also considering placing limits around how clinicians can participate and be assessed as subgroups, particularly if clinician participation in subgroups must be restricted to a single specialty. As a central part of the MVP goals, we believe that the value of subgroup reporting would be for clinicians to be assessed and scored on measures and activities that are applicable to their scope of care while also allowing patients to have greater access to clinician information. We are concerned that we if do not place limitations on how subgroups can be constructed, subgroups could be formed in a way that would result in different types of clinicians assessed on measures that are only applicable to a small subset. We believe that without establishing limitations to subgroup composition prior to implementation, we would not meet the desired programmatic goals of MVPs and in many ways would replicate our concerns with the current state with traditional MIPS. One approach we could consider would be to limit clinicians in multispecialty groups to participate through single-specialty subgroups. Under this approach, we would determine specialty designation as defined by PECOS and are considering if it is feasible for this to be determined at the time of MIPS eligibility determination. We recognize many clinicians have more than one specialty designation in PECOS and may even have multiple PECOS profiles, which contain different specialty designations. We also recognize for many clinician types, the primary specialty designation is related to their clinical degree and not to the type of care they provide (such as PAs, NPs, etc.). To account for differences in care, we could set a threshold to be met in order for a subgroup to be considered a single-specialty subgroup. To align with other thresholds in the Quality Payment Program, such as the requirements for facility-based and hospital-based clinicians, we are considering requiring that 75 percent of clinicians in a subgroup have the same PECOS primary specialty designation or specialty codes on Medicare Part-B claims. This would mean that 75 percent of clinicians in subgroup would need to have the same

primary specialty designation. We believe that this would offer simplicity for clinicians and help assure that clinicians are being assessed with like clinicians within their subgroup on the same measures and activities.

For instance, if anesthesiologists are a part of multispecialty group, we anticipate a future state where the anesthesiologists would form a subgroup and report the *Patient Safety and Support of Positive Experiences with Anesthesia* MVP if it is finalized (detailed in this proposed rule under Table G: Proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year in Appendix 3: MVP Inventory). Under this scenario, the scope of applicable measures in the MVP is narrow and we anticipate that this MVP would be appropriate for limited clinician types, thus a single-specialty subgroup. In another example, if the *Optimizing Chronic Disease Management* MVP (detailed in Appendix 3: MVP Inventory of this proposed rule) is finalized, we could anticipate that a group that included family physicians and cardiologists could form two subgroups, one single-specialty subgroup each for the family physicians and cardiologists, with each subgroup reporting the Optimizing Chronic Disease Management MVP. In this scenario, the family physician subgroup and cardiology subgroup would both be reporting on the same MVP, but they could be selecting different measures/activities from within the MVP as applicable to their scope of practice, as the *Optimizing Chronic Disease Management* MVP is more broadly applicable to a wider range of clinicians.

We do recognize that there may be issues that need to be resolved with this approach. We have concerns about some of the limitations of PECOS, especially for clinician types such as PAs and NPs, whose specialty in PECOS is not related to the scope of care they provide but rather the degree received. We believe that all clinician types are essential to team-based care and request comment on ways to comprehensively categorize clinician specialty. We believe setting a high but not absolute threshold would allow additional flexibilities for subgroups to accurately reflect the care they provide. We do have concerns that this may leave gaps in data because it would not require everyone under a given specialty to report together, may exclude clinicians given the limitations intrinsic to the PECOS system and Medicare Part-B claims data, and could result in clinicians being unable to report in a subgroup based on their specialty designation. For future consideration, we seek comment on setting a threshold for single-specialty subgroups and ways to overcome our concerns. We would also like to consider potential approaches to validating and auditing specialty information. Specialty information could be validated at the time of eligibility determination, during subgroup and MVP registration, or even through attestation. We seek comment on ways we can validate specialty information in a low burden, streamlined manner for future consideration.

Alternatively, we are considering whether subgroup composition could be determined by a different data source. We are interested in ways that we could provide guardrails for subgroups that do not use PECOS or use PECOS information to categorize specialties into specialty families or teams of clinicians who practice in relevant specialties for a given MVP. For ease of readability, we will refer to this concept as specialty families for the remainder of this discussion. Under this alternative, we anticipate that during the subgroup and MVP registration period, a practice administrator or the clinicians in a particular subgroup would attest that the clinicians in a subgroup practice similar scopes of care. We welcome feedback on how specialty families could be identified and what criteria would need to be established for us to set requirements on subgroup formation. For example, specialty families could be constructed similarly to how the Aligned Other Payer Medical Home Model [198] defines primary care focus through identifying multiple specialties to include the following Physician Specialty Codes: 01 General Practice; 08 Family Medicine; 11 Internal Medicine; 16 Obstetrics and Gynecology; 37 Pediatric Medicine; 38 Geriatric Medicine; 50 Nurse Practitioner; 89 Clinical Nurse Specialist; and 97 Physician Assistant. As a third alternative, we have also considered whether we should analyze claims data to identify the primary clinician specialty based on their billing patterns. We believe that this could be a way to help validate subgroup composition for clinicians who practice in more than one specialty. We request comment on these three approaches to setting limitations around the composition of subgroups for future consideration.

As an alternative to establishing limits on how subgroups could be formed, we are also considering adding to the MVP specifications an approved list of specialties and clinician types permitted to report each MVP. Instead of directly limiting the composition of the subgroup, this would limit who can report a given MVP. We believe this option offers additional benefit of not being specific to subgroup reporting but possibly standardizing MVP reporting and impacting clinicians and groups as well. We believe this approach may also promote team-based care and further ensure that MVPs are relevant to those who report them. However, we do have concerns this could have unforeseen consequences in that certain MVPs may be appropriate for specialties not on the designated list, and we would not want to inadvertently place artificial limitations on how clinicians provide care and report to MIPS. We also request comment on this approach for our future consideration.

(v) Request for Information on the Future Vision of Subgroup Reporting

As we look towards future rulemaking, we also request feedback on:

- If the determination of specialty composition should be made during the MVP registration process, as discussed in section IV.A.3.b.(4)(f) of this proposed rule.
- Additional approaches we should consider to incentivize team-based care as we move towards MVP and subgroup implementation.
- If there are other approaches or data sets, in addition to PECOS, that should be considered to classify the scope of care clinicians provide.
- If individual clinicians or groups should attest to their specialty during MVP and subgroup registration.
- If there may be ways to group clinicians in like specialties who may provide similar care and would be interested in reporting the same measures and activities under a given MVP.
- If we should establish criteria or set a threshold for groups to be deemed multispecialty.
- If there are concepts other than specialty that could demonstrate that a subgroup is composed of clinicians who provide care relevant to the MVP the subgroup intends to report.

Overall, we request public comments on how subgroups should be structured, assessed, and scored in a future state as clinicians gain familiarity with the program, more MVPs are developed, and technological advancements allow for low-burden reporting.

[198] § 414.1305.

(4) MVP Requirements

(a) Overview

In the CY 2020 PFS final rule (84 FR 62948), we finalized at § 414.1305 that MIPS Value Pathway means a subset of measures and activities established through rulemaking. We describe our vision for MVPs to connect the four performance categories while using a foundational layer of population health claims-based measures and interoperability, on which to build, quality, cost, and improvement activity linkages. In the CY 2021 PFS final rule (85 FR 84849 through 84859), we finalized a set of MVP development criteria and a process to receive MVP candidates from stakeholders. Through this proposed rule, we are proposing to establish additional MVP related policies to support the implementation and availability of MVPs. In this section, we propose: (1) Refinements to the MVP development criteria; (2) a maintenance process for established MVPs; (3) MVP reporting requirements; and (4) the MVP registration process.

(b) MVP Development and Maintenance

(i) MVP Development Criteria

(A) General MVP Structure

From the time the CY 2021 PFS final rule published, we have solicited feedback from several stakeholders who have submitted MVP candidates for CMS consideration utilizing the MVP candidate solicitation process (85 FR 84854 through 84856). Through this feedback, we have understood that the quality and patient improvement priorities of specialists may differ based on the way they practice. There are clinicians who practice utilizing a team-based approach, involving several clinicians of different specialties working together and for that reason, find quality reporting that reflects that approach more meaningful. Team-based health care is defined by the National Academy of Medicine as ''the provision of health services to individuals, families, and/or their communities by at least two health providers who work collaboratively with patients and their caregivers—to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality care.'' [199] Other clinicians may be specialized in a manner where they focus on a limited number of procedures.

For these reasons, we believe there are various ways to approach MVP development, and the method utilized would be dependent on the topic measured by the MVP. One method is to construct MVPs in a manner that is broad, for example, addressing cancer care comprehensively versus the creation of MVPs for each unique diagnosis of cancer care. Another method is to construct MVPs in a more granular manner, for example, addressing a specific procedure, such as hip and knee arthroplasty. A third approach is to structure MVPs in a manner that reflects a team-based healthcare model. This approach considers the patient's care from a holistic perspective, involving various clinicians as needed. One such example is around surgical care, which involves several clinician types, such as surgeons and anesthesiologists. We believe this approach captures the patient experience and outcomes in a manner that is meaningful, that would result in patient improvement. In the CY 2021 PFS final rule (85 FR 84850), we finalized MVP development criteria that accounts for the development of MVPs collaboratively by multiple specialties for this reason. We believe that the team-based healthcare model has an impact to patient outcomes and encourage the use of this approach, as feasible, when developing MVPs.

In section IV.A.3.b.(4)(b)(ii) of this proposed rule, we discuss a proposed maintenance process for MVPs. In instances where an MVP is initially implemented, for example, to address a specific procedure and there is opportunity to evolve the MVP over time to reflect the team-based healthcare model, we would strongly encourage that transition.

However, we do understand there is not a ''one size fits all'' MVP structure that is suitable for all specialties and believe the use of one of the structure methodologies is appropriate for MVP development.

(B) Selection of Measures and Improvement Activities Within an MVP

As described above, in the CY 2021 PFS final rule (85 FR 84849 through 84850), we established a set of criteria for use in the development and selection of MVPs. Specifically, we had finalized that we were not prescriptive on the number of quality measures that are included in an MVP (85 FR 84850). Through this rulemaking cycle, we are proposing reporting requirements for MVPs, and discuss the allowance of clinician choice in selecting which quality measures and improvement activities to report, as described in detail below in section IV.3.b.(4)(d) of this proposed rule. We believe that it is important to provide clarity in our expectations of the number of quality measures and improvement activities that are available for an MVP Participant to choose.

Generally, an MVP should include a sufficient number of quality measures and improvement activities to allow MVP Participants to select measures and report them to meet the reporting requirements outlined in section IV.3.b.(4)(d) of this proposed rule. To the extent feasible, MVPs should include a maximum of 10 quality measures and 10 improvement activities, to offer MVP Participants some choice without being overwhelming. However, we understand that the total number of measures and activities available in an MVP would depend on the MVP structure. For example, in Appendix 3: MVP Inventory, we are proposing the Optimizing Chronic Disease Management MVP that includes 9 quality measures and 12 improvement activities. Chronic disease can broadly encompass several conditions; therefore, we have selected measures and improvement activities that are closely aligned to the topic and offer clinicians some choice. We refer readers to Appendix 3: MVP Inventory for discussion of our proposed MVPs.

(aa) Requirement of Outcomes or High Priority Measures

In section IV.3.b.(4)(d)(ii) of this proposed rule, we propose MVP quality reporting requirements, that are similar to the requirements of traditional MIPS under § 414.1335. We discuss a proposal to require the reporting of one outcome measure or high priority measure (if an outcome measure is not available). Accordingly, we believe it is important to modify the previously finalized MVP development criteria (85 FR 84849 through 84859), where we describe the criteria for including quality measures in an MVP. We believe we need to update the criteria to ensure MVPs are developed in a manner that accounts for this proposed quality reporting requirement.

(AA) Proposed Outcomes Measures Requirement

Therefore, we propose that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, MVPs must include at least one outcome measure that is relevant to the MVP topic, so MVP Participants are measured on outcomes that are meaningful to the

[199] Mitchell, P., M. Wynia, R. Golden, B. McNellis, S. Okun, C.E. Webb, V. Rohrbach, and I. Von Kohorn. 2012. Core principles & values of effective team-based health care. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. *https://doi.org/10.31478/201210c.*

care they provide. In addition, beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included. This is important since MVPs are proposed to be constructed in a manner that may include one or more clinician specialties, as described above in section IV.3.b.(4)(b)(i)(B)(AA) of this proposed rule, and there should be outcome measures included in the MVP that are relevant to each clinician specialty.

We anticipate over the next few years, there may be opportunities where outcomes-based measures are developed and can be reported utilizing the administrative claims collection type. For example, in the CY 2021 PFS final rule (85 FR 85049 through 85051), we finalized the *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment Systems (MIPS)* outcome-based administrative claims measure. In addition, in Appendix 1: MIPS Quality Measures of this proposed rule, we propose at Table A.4. the *Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System,* which is also an outcome-based administrative claims measure. We propose to allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP. We believe these measures can be used to meet the outcome measure requirement discussed under the MVP reporting requirements in section IV.A.3.b.(4)(d)(ii) of this proposed rule. We request comments on these proposals.

(BB) Proposed Exception When None Are Available

As described in the CY 2021 PFS final rule (85 FR 84850), we are aware that not all specialties and subspecialties may have outcome measures currently available to them in the MIPS program. We are aware of this measurement gap, and believe it is appropriate to allow for the use of high priority measures when outcome measures are not available.

Therefore, we propose that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, in instances when outcome measures are not available, each MVP must include at least one high priority measure that is relevant to the MVP topic, so MVP Participants are measured on high priority measures that are meaningful to the care they provide. In addition, beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, each MVP must include at least one high priority measure that is relevant to each clinician specialty included. This is important since MVPs are proposed to be constructed in a manner that may include one or several clinician specialties, as described above in section IV.3.b.(4)(b)(i)(A) of this proposed rule. As previously established at § 414.1305, we define high priority measures to include outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measures.

We continue to encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking*, to develop outcome measures relevant to their specialty if outcome measures currently do not exist and for eventual inclusion in an MVP. We encourage, to the extent feasible, the inclusion of several outcome and/or high priority measures, if available and relevant to the MVP topic. The inclusion of several measures would allow clinicians to have some choice in selecting the most relevant outcome or high priority measure that is meaningful to their specific practice. We request comments on these proposals.

(bb) Encouragement To Include Patient-Centered Measures

In the CY 2021 PFS final rule (85 FR 84850), we finalized MVP development criteria that takes into consideration the patient voice. Specifically, we finalized MVP development and selection criteria that considers the inclusion of (to the extent feasible), patient-reported outcome measures, patient experience measures, and/or patient satisfaction measures. Through interactions with stakeholders and presentations, we have referred to these measures as patient-centered measures.

We clarify that we are not proposing any revisions to our previously finalized policy, however, we believe it is important that we rely on a consistent understanding of patient-centered measures. Health Affairs [200] stated the following with respect to such measures, ''Measures should be patient-centered and incorporate new approaches to assessing patient health status and patient experience. Such measures include assessment of clinical outcomes, patient-reported outcome measures, as well as new approaches to evaluation of patient experience.'' We request comment on whether there are other aspects of patient measurement that should be considered as a part of the patient-centered measures definition.

We acknowledge that our existing portfolio of patient reported outcome measures is limited and may not be applicable to all specialties and subspecialties. We continue to encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures, described in the CY 2020 PFS final rule (84 FR 62953 through 62955) to develop patient reported outcome measures relevant to their specialty. In addition, we encourage measure stewards of new and existing quality measures in MIPS to consider updating their measures to include the patient centered approach through the measure maintenance cycle or the development of new measures.

(cc) Requirements for QCDR Measures Considered for an MVP

In the CY 2021 PFS final rule (85 FR 84857 through 84859), we finalized that QCDR measures that were approved in the previous year may be considered for inclusion within an MVP. In addition, we finalized at § 414.1400(b)(3)(v)(C)(*4*) that QCDR measures should be fully tested at the clinician level prior to the QCDR measure being included in an MVP. We refer readers to the CY 2021 PFS final rule (85 FR 84857 through 84859) for the specific policies that were previously finalized. Through this proposed rule, we seek to clarify when we would expect a QCDR to prove that their QCDR measure is fully tested before it is implemented within an MVP. QCDRs must self-nominate as a QCDR and submit QCDR measures for CMS consideration within the 60-day self-nomination period that begins on July 1st of the calendar year prior to the applicable performance period and ending on September 1 of the same year. In order to determine whether a QCDR measure may be finalized within an MVP, we will need to receive QCDR measure testing data for review by the end of the self-nomination period, that is no later than September 1 of the year prior to the applicable performance

[200] Higgins, A., D. Safran, N. Fiore, E. Murphy, M. McClellan. 2019. Pathway To Patient-Centered Measurement For Accountability. Health Affairs Blog, Health Affairs. *https://www.healthaffairs.org/do/10.1377/hblog20190910.733376/full/.*

period. We encourage, as feasible, that QCDRs share testing data for their fully tested QCDR measures at the time of MVP candidate submission which may be prior to the September 1st deadline. If a QCDR is unable to submit testing data to demonstrate that their QCDR measure is fully tested at the clinician level by end of the self-nomination period (September 1st) or does not otherwise meet our requirements, we will not finalize the inclusion of the QCDR measure within an MVP.

(C) Foundational Layer

In the CY 2020 PFS final rule (84 FR 62947 through 62948), we establish that the implementation of a foundational population health core measure set using administrative claims-based quality measures that can be broadly applied to communities or populations can result in MVPs that provide more uniformity in how the program measures population health, reduce clinician reporting burden, focuses on important public health priorities, and increases the value of MIPS performance data. In addition, we discuss our beliefs that interoperability is also a foundational element that would apply to all clinicians, regardless of MVP, for whom the Promoting Interoperability performance category is required. Furthermore, we also discuss the importance of the integration of population health measures and Promoting Interoperability measures into MVPs, as they provide a degree of standardization across all clinician types and promotes an infrastructure on which to assess and improve value-based care.

(aa) Population Health Measure

In the CY 2021 PFS final rule, we discuss the inclusion of population health measures calculated from administrative claims-based data as a part of the foundational layer of MVPs, in an effort to improve patient outcomes, reduce reporting burden and costs, and better align with clinician quality improvement efforts. We refer readers to the CY 2021 PFS final rule (85 FR 84856 through 84857) where we discuss population health. Through this proposed rule, we propose: (1) To define the term population health measure; and (2) update the population health measure inventory.

(AA) Proposed Definition

In the 2020 CMS Quality Measure Development Plan—2020 Population Health Environmental Scan and Gap Analysis Report (*https://www.cms.gov/files/zip/2020-mdp-population-health-e-scan.zip*), we conducted an environmental scan to identify gaps in population health measurement within MIPS, specifically for use in the foundational layer of MVPs. Through this environmental scan and gap analysis, we have settled on a definition of ''population health measure''. In addition, as described in the ''Roadmap for Promoting Health Equity and Eliminating Disparities'': *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86046*, developed by the National Quality Forum, health equity continues to be a priority for the agency, we believe it is important to include the measurement of health disparities when measuring population health.

In this proposed rule, we propose to codify this at § 414.1305, such that a population health measure means a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as, access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services. We request comments on this proposal.

(BB) Population Health Measures Inventory

In the CY 2021 PFS final rule (85 FR 84856 through 84857), we finalized the inclusion of the *Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups* as a part of the population health measures within the foundational layer of MVPs.

As described in Appendix 1: MIPS Quality Measure Inventory of this proposed rule, we are proposing to include the *Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions* in the MIPS program. This measure is calculated from administrative claims and measures the annual risk-standardized rate of acute, unplanned hospital admissions among Medicare FFS patients aged 65 years and older with multiple chronic conditions (MCCs). We refer readers to Appendix 1: MIPS Quality Measure Inventory of this proposed rule for additional details on this measure. If finalized, this measure would be an additional population health measure for MVP reporters to submit as part of the Foundational Layer. We have heard from stakeholders the need for more specialty relevant population health measures. We encourage stakeholders to utilize the aforementioned 2020 CMS Quality Measure Development Plan—2020 Population Health Environmental Scan and Gap Analysis Report as a resource to explore population health measure development. Furthermore, we continue to encourage stakeholders to utilize our established Call for Measures process, described in the CY 2020 PFS final rule (84 FR 62953 through 62955) to submit fully developed population health measures for our consideration.

(bb) Promoting Interoperability

In the CY 2021 PFS final rule (85 FR 84849 through 84850), as a part of the MVP development criteria, we had finalized that MVPs must include the full set of Promoting Interoperability measures. Any updates made to the set of Promoting Interoperability measures through traditional MIPS will apply to the MVPs. Therefore, we refer readers to section IV.A.3.d.(4) of this proposed rule where we discuss Promoting Interoperability performance category proposed policies and updates.

(D) Health Equity Measures in MVPs—Request for Information (RFI)

In section IV.A.1.c.(5)(d) of this proposed rule, we discuss our request for information on closing the health equity gap in CMS clinician quality programs, describing our current efforts as an agency, and asking specifically what other efforts can we take within the MIPS program to further bridge the equity gap. We believe there is potential to address health equity specifically through MVPs. As described in Appendix 3: The MVP Inventory, we are proposing improvement activities related to health equity in all 7 proposed MVPs. We also believe there is value in including quality measures that capture health equity in each MVP. However, in evaluating our current measure inventory, we acknowledge that we lack the availability of health equity measures. We intend on prioritizing the development of health equity measures through future cycles of measure development, and would also encourage stakeholders to do the same by utilizing our established processes, such as the Call for Measures: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking,* to develop health equity measures for consideration of the MIPS program and potential inclusion in an MVP. Health equity continues to be a high priority for the agency and for the MIPS program. We envision a future state where health equity measures would be included in all MVPs. We request information on the following:

- Should health equity measures be developed in a manner to be broadly

applicable to the various specialties and subspecialties that participate in MIPS?

- Is there value in the development of more specialty specific health equity measures?
- Considering MIPS and MVPs includes several specialties and subspecialties, what factors should be considered when developing a health equity measure?
- Should we include a health equity measure in the foundational layer of all MVPs, as a required measure, in the future? If not, why not?

(ii) Proposed Maintenance Process for MVPs

We believe it is important that we implement a maintenance process for established MVPs. Independent of the implementation of MVPs; the individual measures typically undergo annual updates and maintenance for several reasons. These updates may include technical coding updates, changes to clinical guidelines, or modifications to various aspects of the measure specification (such as the numerator or denominator). It will be important that we monitor when changes are made to individual measures to ensure that the updated measure is relevant and should be maintained within the MVP.

Therefore, beginning with the CY 2023 MIPS performance period/2024 MIPS payment year, we propose an annual maintenance process for finalized MVPs. In order to ensure that various stakeholder perspectives are also considered, we propose a solicitation process to solicit stakeholder recommendations for potential updates to established MVPs. Under this proposal, beginning in January of the year prior to the performance period, stakeholders could submit their recommendations to revise established MVPs. We would accept stakeholder input on a rolling basis. Any changes to MVPs would be addressed through future notice and comment rulemaking, for example, suggesting the addition or removal of a quality measure or improvement activity. If changes are made to existing individual measures and activities, they would be made under the traditional MIPS performance category policies and criteria for measures and activities and those changes would be reflected within the MVP. We would be unable to communicate with a stakeholder about whether or not their recommendations are accepted ahead of rulemaking. Additional logistical information, such as where to submit recommendations would be provided through the QPP resource library and listserv messaging, prior to the opening of the solicitation process. However, CMS would consult with the stakeholders who originally nominated the MVP about any publicly recommended changes to that MVP. We would be unable to communicate with a stakeholder whether or not their recommendations would be accepted ahead of rulemaking and CMS would ultimately decide whether updates to the established MVPs should be made. To be clear, the annual maintenance process for finalized MVPs would be separate from the new MVP candidate solicitation process that was described in the CY 2021 PFS final rule (85 FR 84854 through 84856). We request comments on these proposals.

(c) Establishing a Portfolio of MVPs

In this proposed rule, we are proposing seven MVPs on the following topics: Rheumatology, Stroke Care, Ischemic Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia. We refer readers to Appendix 3: MVP Inventory for a full description of each MVP, proposal rationale, and where we are soliciting comments.

We anticipate that the portfolio of MVPs would continue to grow over the next few years. Through the review of data received through MIPS reporting for the 2019 performance period, we have identified the ten specialties who have the most participants in the MIPS program. These specialties include primary care, emergency medicine, diagnostic radiology, anesthesiology, cardiology, obstetrics and gynecology, orthopedic surgery, psychiatry, general surgery, and ophthalmology. We believe it is important to develop MVPs that address these specialties, amongst the other specialties that participate in the program. We are, however, aware of the limited availability of relevant cost measures for all specialties and subspecialties and intend to address this concern through this proposed rule. We also refer readers to section IV.A.3.d.(2)(c) of this proposed rule, for our proposal on Cost measure development by stakeholders, where we discuss a potential strategy to mitigate the issue of a limited inventory of cost measures that would potentially remove barriers for MVP implementation.

(d) Proposed MVP Reporting Requirements

(i) Overview

We have reviewed the existing reporting requirements under traditional MIPS and believe that by changing the reporting requirements for MVPs, we would reduce reporting burden. We believe MVP reporting would allow for measurement that is more meaningful by requiring clinicians to report on measures and activities that comprehensively reflect an episode of care or clinical condition. We have heard from stakeholders the importance of having a choice when reporting. In this section, we discuss our proposals for MVP reporting requirements and subgroup reporting limitations for the Quality performance category; Cost performance category; Improvement Activities performance category; and the foundational layer-, which consists of the Promoting Interoperability performance category, and the population health measures.

(ii) Proposed Quality Reporting Requirements in MVPs

Since MVPs would include cohesive and complementary subsets of measures and activities that are relevant and to a given specialty, we believe that MVP Participants would report on measures that provide more meaningful and actionable results. MVP Participants would have the opportunity to select from a subset of measures within an MVP. Furthermore, as discussed above, we believe it is important to continue to require the reporting of outcome and high priority measures in MIPS. Therefore, at § 414.1365(c)(1), we propose that except as provided in paragraph § 414.1365(c)(1)(i), an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure, included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). We discuss in section IV.A.3.b.(4)(b)(i)(B)(aa)(AA) of this proposed rule, that there may be instances where MVPs are developed to include outcomes-based administrative claims measures within the quality component of an MVP, where those measures are not considered to be population-health based. In such instances, we believe it would be appropriate to allow MVP Participants to select to be calculated on the outcomes-based administrative claims measure, at the time of MVP registration, and to allow that measure to meet the outcome measure requirement of MVP quality reporting.

In addition, we have concerns about the ability of small practices to report all required measures in the MVP quality performance category when they select Medicare Part B claims measures as a collection type. In cases when an MVP includes fewer than 4 Medicare Part B claims measures, an MVP Participant in

a small practice would need to report an additional collection type which would add reporting burden. We are concerned that small practices do not have the same resources to meet the quality reporting requirement of 4 measures if the MVP does not include 4 Medicare Part B claims measures. We want to establish policy that does not penalize a small practice for submitting an MVP. Therefore, we propose at § 414.1365(c)(1)(i) that paragraph § 414.1365(c)(1), does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

We request comments on these proposals. We refer readers to section IV.A.3.b.(5)(b)(i) of this proposed rule for details on the MVP quality scoring proposals.

(iii) Proposed Cost Reporting Requirements in MVPs

As MVPs are implemented and available for reporting, each MVP would only include cost measures that are relevant and applicable to the MVP topic. Therefore, the number of cost measures in a given MVP may vary depending on the clinical topic of the MVP. An MVP may include the episode-based cost measures that are relevant to the topic, total per capita cost measure (TPCC), and/or Medicare Spending Per Beneficiary Clinician (MSPB Clinician) measure. As such, we propose at § 414.1365(c)(2) that an MVP Participant is scored on the cost measures included in the MVP they select and report. To be clear, MVP Participants would not submit data for the cost measures; they would be calculated by CMS using administrative claims data, as in traditional MIPS. We request comments on this proposal.

In addition, we refer readers to section IV.A.3.b.(5)(b)(ii) of this proposed rule for details on the MVP cost scoring proposals.

(iv) Proposed Improvement Activity Requirements in MVPs

Similar to the quality performance category within MVPs, we also believe the improvement activities performance category should provide clinicians with an opportunity to select from a subset of improvement activities within an MVP that are relevant to the clinical topic being measured. Therefore, at § 414.1365(c)(3), we propose that MVP Participant who reports an MVP, must report one of the following: Two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice as described at (82 FR 53652) and at § 414.1380(b)(3)(ii). We note that these proposed MVP improvement activity requirements are reduced in comparison to what is required in traditional MIPS (82 FR 53652) under which we generally require two high-weighted activities, one high-weighted and two medium-weighted activities, four medium-weighted activities, or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice. We believe reduced reporting requirements are necessary to support adoption of and reduce burden for implementation of MVPs. We request comments on this proposal and refer readers to section IV.A.3.b.(5)(b)(iii) of this proposed rule for proposals related to MVP improvement activities scoring and discussion of why improvement activities are double-weighted under MVP reporting.

(v) Proposed Reporting Requirements for the Foundational Layer

(A) Promoting Interoperability

(aa) Proposed Reporting Requirements

As described in the CY 2021 PFS final rule (85 FR 84849 through 84853), all MVPs should include the entire set of Promoting Interoperability measures, as a part of the foundational layer. We do not intend to establish different reporting requirements for Promoting Interoperability for MVPs from what is established under traditional MIPS. Therefore, we propose at § 414.1365(c)(4)(i) that an MVP Participant, is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b). We request comments on this proposal and refer readers to section IV.A.3.b.(5)(b)(iv) of this proposed rule for details on the proposals for MVP Promoting Interoperability scoring and reweighting.

(bb) Subgroup Limitations

As noted in section IV.A.3.b.(3) of this proposed rule, we believe that subgroups should be assessed using subgroup level data to the extent that it is operationally feasible. However, through the MVP Town Hall (85 FR 84846), we heard from stakeholders that some clinicians would need additional time to resolve operational challenges, including challenges related to configuration of EHR systems. Given these operational challenges, as well as other considerations specific to the Promoting Interoperability performance category, we believe that each subgroup should submit their affiliated group's data for the Promoting Interoperability performance category and receive a score based on that data. We acknowledge that requiring each subgroup to submit their affiliated group's data could result in duplicative reporting of the same data if their affiliated group also reports as a group for the Promoting Interoperability performance category. However, we believe that this approach is the most appropriate way to address the operational challenges identified by stakeholders and other issues specific to the Promoting Interoperability performance category. For instance, requiring clinicians to report Promoting Interoperability by subgroup may initially disincentivize clinicians from choosing to report MVPs as it may exacerbate the reporting burden and use of resources by a smaller cohort of clinicians. Furthermore, the Promoting Interoperability measures are applicable to many clinician types and are not designed to be specialty specific like the quality measures, therefore, it is unclear whether an advantage of assessing Promoting Interoperability performance on a subgroup of clinicians exists. Other performance categories include specialty specific measures, where assessment of performance at the subgroup level may be more meaningful. Therefore, we propose at § 414.1365(c)(4)(i)(A) that for the CY 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years, to require an MVP Participant that is a subgroup to submit its affiliated group's data for the Promoting Interoperability performance category. The submission of the affiliated group's data would be on the subgroup's behalf. If the affiliated group chooses to report as a group for the Promoting Interoperability performance category, the group still would be required to submit its own data separately and pursuant to the reporting rules for groups.

Alternatively, we considered proposing that for the 2023 and 2024 MIPS performance periods/2025 and 2026 MIPS payment years that each subgroup would be required to submit either their affiliated group's data or their subgroup data for the Promoting Interoperability performance category. We considered requiring subgroups to indicate whether they would be submitting data for the Promoting Interoperability performance category at the group or subgroup level. However, we believe that the advantages of

reporting Promoting Interoperability performance category data at the subgroup level are not clear at this time and such a proposal, may introduce additional and unnecessary complexity.

In a future state, we could reassess whether subgroups should be required to submit subgroup level performance data for the Promoting Interoperability performance category. We refer readers to section IV.A.1.c.(5) of this proposed rule for details on the Digital Quality Measurement Blueprint and the Fast Healthcare Interoperability Resources (FHIR)-standard. Some subgroups may prefer to have the ability to report Promoting Interoperability performance category data at the subgroup level.

We request public comment on whether subgroups should be allowed or required to submit subgroup level performance data for the Promoting Interoperability performance category beginning with the performance period in 2023/2025 MIPS payment year, or in the future. We also request comment on any technical challenges that clinicians may encounter in reporting on Promoting Interoperability measures for a subgroup using technology certified to the existing certification criteria for reporting and capturing this information at § 170.315(g)(1) and (2). In addition, we request public comment on the aforementioned issues that would give us a better understanding on whether we should reconsider subgroup reporting in the future.

As previously discussed in the CY 2020 PFS proposed rule (84 FR 40734), in future years we may consider customizing the Promoting Interoperability measures in each MVP and we are seeking comment on how the Promoting Interoperability performance category could evolve in the future to meet our goal of greater cohesion between the MIPS performance categories. We believe that eligible clinicians could benefit from more targeted approaches to assessing the meaningful use of certified EHR technology which aligns with clinically relevant MVPs cutting across the MIPS performance categories. For instance, we may consider how measures in the Promoting Interoperability performance could align with specific MVPs.

We may also consider developing Promoting Interoperability measures which are better tailored to specific MVPs, or that seek to assess the use of health IT associated with reporting measures in other categories and could be paired with these measures under an MVP. Finally, we may consider whether existing Promoting Interoperability measures could be tailored to specific populations addressed under an MVP. We invite comment on these concepts, as well as other suggestions for how the Promoting Interoperability performance category could align with the MVP framework in the future.

(B) Population Health Measures

As described in the CY 2017 Quality Payment Program final rule (81 FR 77130 through 77136) we had received public comment that not all population health measures are applicable or attributable to all specialties. In order to mitigate this concern, at § 414.1365(c)(4)(ii), we propose that an MVP Participant is scored on 1 population health measure in accordance with paragraph § 414.1365(d)(1). To be clear, the population health measure calculation does not contribute to the required reporting of four quality measures, as described at § 414.1365(c)(1) and in section IV.A.3.b.(4)(d)(ii) of this proposed rule. Since the aforementioned population health measures are administrative claims based, they do not require data submission from clinicians. Therefore, it is important that an election period is established in which MIPS eligible clinicians, groups, subgroups, and APM entities would identify which MVP and population health measure they intend to report. We refer readers to the proposed registration process below and intend to provide additional guidance through subregulatory means.

In crafting our proposal, we also considered the alternative where we wouldn't require MVP participants to select which population health measure to be calculated on. Under this alternative considered, we would require and calculate both population health measures and apply the higher score to the quality score. While we thought this approach would reduce some of the burden associated with requiring this selection at the time of MVP registration, we ultimately decided to propose to allow MVP participants to select which population health measure to be calculated on. As discussed above, this selection process is being proposed in an effort to mitigate some of the previously stated concerns stakeholders had with these measures.

We request comments on our proposal as discussed above and refer readers to section IV.A.3.b.(5) of this proposed rule for details on the scoring of population health measures.

(vi) Subgroup Reporting

(A) Subgroup Reporting Overview

As discussed in section IV.A.3.b.(3) of this proposed rule, subgroup reporting would provide an avenue for clinician teams within a larger group to be able to submit MVPs that are clinically relevant to them and would be a first step in allowing more granular clinician information to be made available to patients. To generate more clinically relevant and granular information about clinician performance, we believe that subgroups should be assessed using subgroup level data to the extent that it is operationally feasible. We anticipate more granular data would be available for patients, clinicians, and other stakeholders through a three-pronged approach of mandatory subgroup reporting, broad use of standards-based APIs that leverage the FHIR standard and the creation and use of dQMs as discussed in section IV.A.1.c.(5) of this proposed rule. We believe that subgroups should report data for the quality and improvement activities performance categories as a subgroup. The cost performance category does not require data submission; however, as described in section IV.A.3.b.(5)(b)(ii) of this proposed rule, we believe cost data should be assessed at the subgroup level as well.

(B) Proposed Subgroup Reporting Limits

As described in section IV.A.3.b.(2)(d)(i) of this proposed rule, we are proposing voluntary reporting of MVPs as a gradual approach to prepare stakeholders through the transition plan for MIPS before eventually requiring reporting through an MVP or the APP. As a part of the transition, we discuss our intention to continue to offer reporting through traditional MIPS at the group level, as discussed in section IV.A.3.b.(4)(d), to allow clinicians and groups additional time to continue reporting in traditional MIPS while we work expand the inventory of MVPs over the next few years.

While we intend to allow for this flexibility through the transition, we believe that groups should only form subgroups if they are reporting through an MVP or the APP and not through traditional MIPS. As such, we propose at § 414.1318(c)(2) that individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all of the MIPS performance categories based on an MVP in accordance with § 414.1365, and on the APP in accordance with § 414.1367, as applicable. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b). This includes MIPS eligible clinicians who are APM participants that choose to report on an MVP as a subgroup. We believe

encouraging the subgroup reporting in MVPs is an important step to help MVP Participants transition to MVP reporting in the future.

As stated in the CY 2021 PFS final rule (85 FR 84846), we envisioned subgroup reporting would be implemented for multispecialty groups reporting MVPs. A subset of a TIN could form a subgroup if they are part of the same TIN, but could not form a subgroup if they are part of different TINs. For example, a group consisting of a single billing TIN that contains a number of participants in the same APM Entity, could form a subgroup to report an MVP or the APP. However, an APM Entity could not select eligible clinicians who are part of different TINs, based on their specialty, and report as a single subgroup. We refer readers to section IV.A.3.b.(2)(e) of this proposed rule, where we discuss subgroups reporting the APP. Due to operational and technical issues described above, we do not believe it is feasible to permit MIPS eligible clinicians in multiple TINs to form a subgroup to report MVPs or the APP. We request public comment on whether there are strategies we should consider to enable formation of subgroups comprised of MIPS eligible clinicians from multiple billing TINS to report MVPs or the APP.

We request public comment on this proposal.

(vii) Proposed MVP Reporting Requirements Summary

Table 34 summarizes the proposed MVP reporting requirements:

TABLE 34: Proposed MVP Reporting Requirements

Quality Performance Category*	Improvement Activities Performance Category*	Cost Performance Category
An MVP Participant selects 4 quality measures, 1 must be an outcome measure (or a high priority measure if an outcome is not available or applicable). *As applicable, an administrative claims measure, that is outcome-based, may be selected at the time of MVP registration to meet the outcome measure requirement.*	MVP Participant selects: Two medium weighted improvement activities **OR** One high weighted improvement activity. **OR** Participates in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at (82 FR 53652) and at § 414.1380(b)(3)(ii)	An MVP Participant, is scored on the cost measures that are included in the MVP that they select and report.
Foundational Layer (MVP agnostic) **Population Health Measures*** An MVP Participant selects 1 population health measure, at the time of MVP registration, to be scored on. The results are added to the quality performance category score. **Promoting Interoperability (PI) Performance Category** An MVP Participant is required to meet the Promoting Interoperability performance category requirements at § 414.1375(b).		

*Indicates MVP Participant may select measures and/or improvement activities.

(e) Third Party Intermediaries Reporting MVPs

We believe it is also important to ensure that third party intermediaries have the capabilities to support MVPs. We refer readers to section IV.A.3.h. of this proposed rule for proposals related to requiring third party intermediaries to support MVP and subgroup reporting.

(f) MVP Participant Registration

We strive to limit administrative burden and offer as much flexibility as possible. With this principle in mind, we propose steps that an MVP Participant must take to inform CMS of their participation and submission options, with certain exceptions for when the method of collection requires the information in advance of the performance period or we do not have any discretion (such as in virtual groups). We believe that a registration process would be easiest and the most efficient option for MVP Participants and CMS to accurately capture: (1) MVP selection; (2) population health measure selection; (3) administrative claim-based quality measure selection; and (4) subgroup participation.

(i) Proposed Registration Timeline

(A) General Timeline

We considered whether registration should occur at the time of data submission (as described at § 414.1325(e)) or at a specific point during the performance period (for example, by July 1 of the applicable performance period to coincide with the CAHPS for MIPS registration period (81 FR 77072)). On January 7, 2021, we held the MVP Town Hall (85 FR 74729) and publicly shared the MVP Town Hall Preparation Guide,[201] as well as these two potential options and solicited feedback from stakeholders.

This first option would require registering at the time of performance data submission because: It would provide clinicians additional time and flexibility to submit the identification information; better account for TIN/NPI changes during the performance period; allow third-party intermediaries time to accommodate reporting; streamline

[201] MVP Town Hall Preparation Guide (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1233/MVP%20Town%20Hall%20Preparation%20Guide.pdf*).

reporting; minimize burden; allow time to review APM participation lists and confirm QP status in order to determine the clinicians to be included in subgroups. Many commenters supported this. A few commenters recommended that the election process take place during the performance period in conjunction with the CAHPS for MIPS registration process and stated that the increased burden associated in enrolling clinicians in a subgroup during the performance period was worth it for subgroups to be scored on administrative claims quality measures and cost measures specific to their subgroup.

We also considered the second option: Having the registration window coincide with performance data submission given that this would provide the additional time and flexibility for clinicians and practices to identify the clinicians in a subgroup. Even though this option would not require a prior registration process to identify clinicians in a subgroup and would allow groups to internally account for clinicians joining or leaving their group throughout the performance period, it would also have significant tradeoffs such as not allowing enough time for CMS to provide enhanced performance feedback as proposed in section IV.A.3.b.(5)(d) of this proposed rule. We are also concerned that this option would result in subgroups that are assessed on less information due to insufficient operational time for CMS to pull and reconcile claims data and CAHPS beneficiary sampling for the subgroup that informs performance measurement of the subgroup. Furthermore, this option would also require clinicians in subgroups to be assessed on the overall group's administrative claims quality measures and cost measures instead of the subgroup's performance on those measures; this means that if subgroups would like to be assessed on the subgroup level for claims data and CAHPS, this would delay feedback and scoring.

In consideration of stakeholder feedback and to ensure timelines are feasible for CMS and stakeholders alike, we believe the first option is more appropriate—a registration period that begins on April 1st and ends November 30th of the applicable performance period (h). Therefore, we propose at § 414.1365(b)(1), that to report an MVP, an MVP Participant must register for the MVP, and if applicable, as a subgroup during a period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. Under this proposal, to report the CAHPS for MIPS survey associated with an MVP, a group, subgroup, or APM entity must complete their registration by June 30 of such performance period or a later date specified by CMS.

We believe the benefits of aligning MVP, MVP population health measure, and subgroup registration during the performance period, outweigh the limitations of performance period registration. Through the MVP town hall, we have heard stakeholders indicate that a registration period that is held during the performance period is limiting because it provides clinicians with less time to decide which MVP they would like to report or make changes to their selection. However, we believe that this would encourage clinicians to identify important MVP topics early on in the performance period, in which they can focus their quality improvement efforts on. Also, this would allow us sufficient time to identify clinician participation in subgroups and provide more granular and meaningful subgroup performance feedback to inform quality improvement and patient choice resulting in clinician assessment on more information relevant to their subgroups, such as targeted administrative claims quality measures and cost measures.

In addition, we believe that the proposed registration period would allow more flexibility in the creation of subgroups that represent clinical alignment and to add or remove clinicians from the subgroup, or otherwise, make changes to their participation status in subgroups, before the end of the registration period.

We request public comment on our proposals as discussed above.

(B) Exception for MVP Participants That Want To Report the CAHPS for MIPS Survey Measure

Currently, as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77072), groups that register to administer the CAHPS for MIPS survey measure prior to the registration deadline could cancel their registration or change their CAHPS for MIPS survey selection before the close of registration on June 30th. In this proposed rule, we propose at § 414.1365(b)(1) that in order for an MVP Participant to report the CAHPS for MIPS survey measure associated with an MVP, a group, subgroup, or APM entity would need to register by the same deadline as the CAHPS for MIPS registration, which is June 30 of the applicable 12-month performance period (81 FR 77072).

Under this proposal, clinicians participating in subgroups or groups reporting on the CAHPS for MIPS survey measure within an MVP would be unable to make any changes to their participation in the CAHPS for MIPS survey beginning July 1 of the applicable performance period. We note that clinicians in subgroups who do not intend to report the CAHPS for MIPS measure would still be able to make changes to their participation status in subgroups before the registration period ends on November 30th.

We request public comment on these proposals.

(ii) Proposed MVP Participant Registration Requirements

We believe there are certain elements of information that are important to include at the time of MVP registration. Specifically, we propose at § 414.1365(b)(2)(i) and (ii), that at the time of registration, an MVP Participant must submit the following information, as applicable: (1) Each MVP Participant must select an MVP, 1 population health measure included in the MVP, and if applicable, any outcomes-based administrative claims measure on which the MVP Participant intends to be scored; (2) Each subgroup must submit a list of each TIN/NPI associated with the subgroup which identifies each individual eligible clinician NPI in the applicable subgroup for the group TIN and a plain language name for the subgroup. The following subsections discuss each of these elements.

(A) MVP Selection

To accurately capture who is participating in MVP reporting, it is important to establish the use of identifiers to identify what is intended to be reported, and by whom. We intend to publish a list of MVPs that have been finalized in rulemaking in the prior year, with identifiers available for a given performance period on the QPP Resource Library, prior to the start of the registration period, along with registration guidance. Therefore, we propose that the MVP Participants must select a specific MVP, at the time of registration, as described at proposed § 414.1365(b)(2)(i). Under this proposal, MVP Participants would not be able to submit or make changes to the MVPs they select after the close of the registration period, and therefore, would not be allowed to report on an MVP they did not register for. We request comments on this proposal.

In addition, for our consideration for future rulemaking, we request public comment on whether MVP Participants would be interested in the ability to select multiple MVPs at the time of registration. If so, we would like to

understand what value MVP Participants might find with this allowance. Specifically, we would like to know if MVP Participants believe they will likely report on multiple MVPs. Also, we would like to know if MVP Participants would want to submit data on multiple MVPs. We also refer readers to section IV.A.3.b.(3)(h) of this proposed rule, where we discuss a similar comment request for subgroups.

(B) Population Health Measure Selection

Similarly, we plan to publish a list of the population health measures that have been finalized for a given performance period on the QPP Resource Library. We plan for this to occur prior to the start of the registration period, along with posting registration guidance. As proposed in section IV.A.3.b.(4)(d)(V)(B) of this proposed rule, we propose that MVP Participants who report an MVP, must submit one population health measure of their choice from the list of finalized population health measures within the foundational layer of the MVPs. The two proposed and previously finalized population health measures are both administrative claims based, and do not require physical data submission by clinicians. Therefore, in order for this selection to be tracked, we propose at § 414.1365(b)(4)(i) that MVP Participants would be required to select this population health measure at the time of registration. Under this proposal, MVP Participants would not be able to submit or make changes to the selected population health measure after the close of the registration period. In addition, MVP Participants would not be able to successfully register to report an MVP if they do not select a population health measure, as the registration would be considered incomplete. We request comments on this proposal.

(C) Outcomes-Based Administrative Claims Measure Selection

Within the MIPS quality performance category quality measure portfolio, there are some MIPS quality measures that are outcomes-based and utilize the administrative claims-based collection type. There are instances in which these measures are not identified as population health measures. For example, because the measure related to a specific procedure such as hip and knee arthroplasty we do not define this as population health since it does not necessarily impact the health of a population. While these measures may not be population health measures, they still reflect important clinical concepts and practices that are important to clinicians and lead to improved patient outcomes. Therefore, we believe it is important to not exclude these measures from MVPs. Depending on the MVP topic, these quality measures may be applicable and relevant to the topic being measured. In addition, administrative claims-based measures reduce reporting burden placed on clinicians because CMS calculates these measures utilizing administrative claims data. As such, we propose at § 414.1365(b)(2)(i) that the MVP Participant must select any outcomes-based administrative claims measures on which the MVP Participant intends to be scored. As proposed in section IV.A.3.b.(4)(d)(ii) above in this proposed rule and at § 414.1365(c)(1), an MVP Participant must select and report 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP. As applicable, an outcomes-based administrative claims measure, may be selected at the time of MVP registration to meet the outcome measure requirement (excluding the population health measures required under § 414.1365(c)(4)(ii)). We request comments on this proposal.

(D) Subgroup Participants

As part of the registration process, to accurately capture all the clinicians participating in a subgroup, we propose at § 414.1365(b)(2)(ii) that each subgroup must submit: (1) A list of each TIN/NPI associated with the subgroup, which should identify each individual eligible clinician NPI in the applicable subgroup for the group TIN; and (2) the subgroup's name in a plain language manner.

We believe that the subgroup names would help communicate the specialty, location, or other relevant information which would be displayed on the Compare Tools, helping stakeholders differentiate between subgroups. We plan to provide additional guidance for the template in subregulatory guidance for the nomenclature of subgroups and intend to provide a template and guidance to clinicians and practices on the use of plain language for naming subgroups. For example, a subgroup which consists of oncologists in the Mayberry location of one overall group TIN who chooses to report the Oncology MVP could be called Mayberry Oncology. We considered an alternative option to allow flexibility for groups to choose their own naming convention for subgroups. We are concerned that this option may result in the use of naming conventions that may not be meaningful for patients. Additionally, we believe that this option may increase operational complexity for CMS and stakeholders due to the potential for duplicate naming of subgroups.

Upon successful registration submission, we would assign a unique subgroup identifier. This subgroup identifier would be separate from the individual NPI identifier, the group TIN identifier, and the MVP identifier, discussed in this proposed rule. We would maintain the same identifier year over year, as applicable. In scenarios where a subgroup's makeup changes, which will be identified at the time of registration, we will issue the subgroup a new identifier. We believe this identifier is also needed to allow third-party intermediaries to capture and submit performance data for clinicians participating in subgroup reporting as discussed in section IV.A.3.h.(2)(b) of this proposed rule.

We request public comment on these proposals. Additionally, we request feedback on if there are any additional operational considerations or recommendations for the implementation of this policy for future consideration.

(iii) Summary of the Overall Proposed Registration Process

Table 35 presents a comprehensive perspective of the overall proposed registration timeline:

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TABLE 35: Proposed Registration Process for MVP and Subgroup Elections Beginning with the CY 2023 MIPS Performance Period

April 1st of the applicable performance period, or a later date specified by CMS	MVP Participants may begin to register for MVP reporting.
June 30th of the applicable performance period, or a later date specified by CMS	Groups, subgroups, APM entities, who intend to report the CAHPS for MIPS Survey Measure through an MVP, must submit: • MVP selection and population health measure selection • As applicable, select an outcomes-based administrative claims measure that is associated with an MVP. • As applicable, each subgroup must submit a list of each TIN/NPI associated with the subgroup. • As applicable, each subgroup must submit a plain language name for the subgroup. • Separately register through the MIPS registration system by June 30th to participate in the CAHPS for MIPS Survey.
November 30th of the applicable performance period, or a later date specified by CMS	The registration period closes. New registrations or changes to registration would not be accepted after November 30th. MVP Participants cannot make any changes to registration of: • MVP selection • Population health measure selection • As applicable, the selection of an outcomes-based administrative claims measure associated with the MVP • As applicable, the list of each TIN/NPI associated with the subgroup. • As applicable, subgroup participation (including the subgroup's plan language name).

Table 36 presents a crosswalk of the various clinician types, the information expected at the time of registration, and a reminder of the MVP reporting requirements if our proposals are finalized as proposed.

TABLE 36: How MVP Reporting Would Work

Who Reports	Information Required at the time of MVP Registration	MVP Reporting Requirements
Years 1-2 (2023 and 2024)		
Individual Clinicians	MVP selection, Population Health Measure selection, and (as applicable) outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
Groups	MVP selection, Population Health Measure selection, and (as applicable) administrative-claims based measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1. Members of the group would be required to report on the same measures and activities within an MVP.
Subgroups	MVP selection, Population Health Measure selection, (as applicable) the outcomes-based administrative claims measure selection, and the subgroup participant information described at § 414.1365(b)(2). *Subgroups would also receive a subgroup identifier from CMS at the time of registration.*	Requirements in table 1. Members of the subgroup would be required to report on the same measures and activities within an MVP.
APM Entities	MVP selection, Population Health Measure selection, and as applicable outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
Year 3 and Future Years (2025 and beyond)		
Individual Clinicians	MVP selection, Population Health Measure selection, and (as applicable) outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
Single Specialty Groups[+]	MVP selection, Population Health Measure selection, and (as applicable) outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1. Members of the group would be required to report on the same measures and activities within an MVP.
Subgroups	MVP selection, Population Health Measure selection, (as applicable) outcomes-based administrative claims measure selection, and the subgroup participant information described at § 414.1365(b)(2). *Subgroups would also receive a subgroup identifier from CMS at the time of registration.*	Requirements in table 1. Members of the subgroup would be required to report on the same measures and activities within an MVP.
APM Entities	MVP selection, Population Health Measure selection, and as applicable outcomes-based administrative claims measure selection, as proposed at § 414.1365(b)(2).	Requirements in table 1.
[+]*Multispecialty Groups would be required to form subgroups to report an MVP.* We refer readers to § 414.1305 for the definitions of MVP Participant, single specialty group, multispecialty group, and subgroup.		

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(5) Scoring MVP Performance

(a) Overview of MVP Scoring

In the CY 2020 PFS proposed rule, we requested comments on how we should address scoring policies as we transition to MVPs (84 FR 40741 through 40742). Generally, commenters indicated scoring for MVPs should include policies for simplification and alignment of the scores for measures and activities within the performance categories and the final score. We subsequently held an MVP Town Hall on January 7, 2021 (85 FR 74729 through 74730) and publicly shared the MVP Town Hall Preparation Guide (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1233/MVP%20Town%20Hall%20Preparation%20Guide.pdf*) to aid MVP Town Hall participants in understanding the direction we may take with MVPs scoring. We received feedback opposing the use of policies that may differentiate the way we score measures and activities within MVPs compared to traditional MIPS because of concerns over adding complexity to the program. Stakeholders urged us to apply simple scoring rules for MVPs whenever possible to ease burden and help clinicians to predict and understand their MVP scores. Wherever possible, stakeholders requested that we align with traditional MIPS scoring.

In general, in this proposed rule, we propose to score MVPs similar to policies established for traditional MIPS, including without limitation the methodology to score MVP Participants based on their performance on measures and activities in the four performance categories; performance standards for each of the performance categories; calculation of achievement and improvement scores; and calculation of the final score. We strive to ensure our methodology to convert the scores of activities and measures into a final score balances the statutory requirements and goals of the program with the ease of use, stability, and meaningfulness to MIPS eligible clinicians (83 FR 59840). Our proposed scoring methodology would allow for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians (85 FR 50305). We believe these proposed scoring policies would ensure the meaningful evaluation of performance of MVP Participants based on measures and activities in the MVP. Several of the proposed MVP specific scoring policies would support our identified goal to simplify the program by offering MVPs that link clinically relevant measures and activities, which are meaningful to clinicians, patients, and the program.

We propose at § 414.1365(d)(1) that an MVP Participant that is not an APM Entity is scored on measures and activities included in the MVP in accordance with paragraphs § 414.1365(d)(1) through § 414.1365(d)(3). We also propose at § 414.1365(d)(1) that an MVP Participant that is an APM Entity is scored on measures and activities included in the MVP in accordance with § 414.1317(b). Additionally, we propose at § 414.1365(d)(2) that unless otherwise indicated in § 414.1365(d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP. Lastly, we propose at § 414.1365(d)(3) that an MVP Participant is scored under MIPS in four performance categories.

We request public comments on these proposals.

In sections IV.A.3.b.(5)(b) and IV.A.3.b.(5)(c) we propose scoring policies for MVPs that address scoring population health measures within the quality performance category, scoring an outcomes-based administrative claims measure selected as an outcome measure at the time of registration, scoring only the cost measures specified in the MVP for the cost performance category, assigning 20 points for each medium-weighted and 40 points for each high-weighted improvement activity in the improvement performance category, scoring subgroups on the Promoting Interoperability performance category using the affiliated group score, circumstances in which we would reweight performance categories within an MVP, and application of the complex patient bonus to MVPs. We also propose using enhanced performance feedback in MVPs.

As discussed in section IV.A.3.b.(5)(b), we propose scoring policies that apply to MVP Participants. We do not anticipate the need for separate scoring policies for MVPs that might be reported by a single specialty, for example a group of specialists that perform the procedure addressed by an MVP, or for MVPs that could be reported by multiple specialties engaged in team-based care; we believe all scoring policies would apply in each scenario.

(b) Performance Category Scores

(i) Scoring the Quality Performance Category in MVPs

(A) Scoring Based on Achievement

We propose to maintain scoring policies finalized in traditional MIPS for MVPs to leverage meaningful scoring policies and retain stable scoring for MVP Participants. We refer readers to § 414.1380(b)(1)(i) for details on our policies for scoring performance on quality measures for traditional MIPS (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, 84 FR 63011 through 63019, and 85 FR 84904 through 84906). Our proposed policies for scoring quality in traditional MIPS are described in further detail in section IV.A.3.e.(1)(c) of this proposed rule. We refer readers to section IV.A.3.e.(1)(c)(iii) of this proposed rule for our proposals to remove the 3-point floor for Class 1 and Class 2 measures for the 2024 MIPS payment year for traditional MIPS, and for Class 4 measures (new measures) to provide a score from 5 to 10 points in the first two performance periods a measure is used in MIPS. We propose to align with these policies as well to maintain consistency between MVPs and traditional MIPS.

We propose at § 414.1365(d)(3)(i) that, except as provided in paragraphs (d)(3)(i)(A)(1) and (B), the quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

(B) Population Health Measures

Population health measures are administrative claims measures that are part of the foundational layer of MVPs, as described in section IV.A.3.b.(4)(b)(i)(C)(aa) of this proposed rule. As proposed in section IV.A.3.b.(4)(f)(ii)(B) of this proposed rule, MVP participants would select a population health measure during the registration process. We would score the selected measure as proposed at § 414.1365(d)(3)(i). Since we are proposing to adopt our scoring policies used in traditional MIPS for MVPs, we would exclude the measure from the total achievement points and the total available points if the administrative claims measure does not have a benchmark or meet the case minimum requirement in accordance with § 414.1380(b)(1)(i)(A)(2)(ii). We propose at § 414.1365(d)(3)(i)(A) that except as provided in paragraph (d)(3)(i)(A)(1) each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

We are concerned about the ability of subgroups to meet the case minimum for an administrative claims measure but are interested in including population health measures in the subgroup's score for the MVP. We propose at § 414.1365(d)(3)(i)(A)(1) that subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available. We believe this is appropriate because we believe it is important for subgroups to be scored on population health measures, and we believe that the groups score will be reflective of the subgroup's performance on population health measures. We also propose at § 414.1365(d)(3)(i)(A)(1) if the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

We request public comments on this proposal.

We note that we are also concerned about scoring individual clinicians on population health measures. Because population health measures have measured the quality of a population or cohort's overall health and well-being, we historically have required a minimum reliability standard of 0.4 which for most measures equates to a high case minimum in order to be

scored. We believe it will be common that a solo practitioner, or an individual clinician that is part of a group but chooses to be scored as an individual clinician will not be scored on population health measures. In these scenarios, we would remove the population health measure from the denominator in accordance with § 414.1380(b)(1)(i)(A)(2)(ii). Historically, we have not combined performance for the individual clinician with performance from the group and therefore have concerns with using the group score for individual clinicians who cannot be scored for population health measures. We understand there may be concerns from stakeholders on scoring individual clinicians on broad population health measures. However, we request comment on approaches to scoring individual clinicians on population health measures given the importance of these measures.

We request public comments on this proposal.

(C) Outcomes-Based Administrative Claims Measures

We want to clarify that MVPs may include outcomes-based administrative claims measures that are identified as outcome measures but are not population health measures as defined at § 414.1305. As described in section IV.A.3.b.(4)(f)(ii)(C) of this proposed rule, clinicians will be able to select outcomes-based administrative claims measures as their required outcome measure during MVP registration, if an outcomes-based administrative claims measure is available within the MVP. For example, if a clinician selects an outcomes-based administrative claims measure during registration to be used as an outcome measure and submits three additional measures, and the outcomes-based administrative claims measure has a benchmark and meets the case minimum, all four measures will be scored. If the clinician selects an outcomes-based administrative claim measure to fulfill their outcome measure requirement, and the outcomes-based administrative claims measure does not meet the benchmark or meet the case minimum. Therefore, we propose at § 414.1365(d)(3)(i)(B) that MVP Participants receive zero measure achievement points for each selected outcomes-based administrative claims measure that does not have a benchmark or meet the case minimum requirement. This scoring aligns with our proposal at IV.A.3.e.(1)(c) of this proposed rule to score Class 2 measures in traditional MIPS. If the clinician selects the outcomes-based administrative claims measure, which can be calculated and submits more than three measures, including an additional outcome measure, scores from the highest four measures will be used to determine the quality performance category score.

Below is an example of scoring for a MIPS eligible clinician who selects an outcomes-based administrative claims measure as the required outcome measure, does not meet case minimum for the measure, and does not submit an additional outcome measure to meet the outcome measure requirement:

- *Measure #1: 10/10 points.*
- *Measure #2: 10/10 points.*
- *Measure #3: 10/10 points.*
- *Outcomes-based administrative claims measure: Does not meet case minimum, no other outcome measure submitted: 0/10 points.*
- *Total quality performance category points: 30/40.*

We request comment on this proposal.

(D) Scoring for MVP Participants That Do Not Meet the Quality Performance Category Requirements

We believe it is important that MVP Participants submit the required quality measures specified in the MVP they selected to report. For traditional MIPS, we implemented a validation process to determine if measures are available and applicable (81 FR 77290 through 77291, and 82 FR 30108 through 30109). We have received feedback from stakeholders that this process may be confusing for clinicians. We do not believe we need a validation process to determine the availability and applicability of measures for MVP Participants because MVPs will focus on a condition or specialty, and we believe MVPs will be selected and reported because of the MVP applicability to their practice and patients.

(E) Scoring Example

Table 37 includes examples of scoring within the quality performance category for MVPs. Quality scoring example #1 includes a group that reports four measures and has one population health measure automatically calculated for them and receives 2 percentage points for improvement scoring for an MVP. For quality scoring example #2, the group is a small practice who reports all the Medicare Part B claims measures in an MVP. Because there are only three Medicare Part B claims measures available in this example, the group has a reduced denominator, so the group is not penalized for not reporting four quality measures specified in MVP reporting requirements. The second example also includes 2 percentage points for improvement scoring.

TABLE 37: Example MVP to Demonstrate Quality Performance Category Scoring

Objective	**Quality Scoring Example #1** All measures can be scored	**Quality Scoring Example #2** Medicare Part B
Quality measures (four)	Measure #1: 10/10 points Measure #2: 5/10 points Measure #3: 5/10 points Measure #4: 8/10 points	Measure #1: 10/10 points Measure #2: 5/10 points Measure #3: 8/10 points Measure #4: *4th Medicare Part B measure not available, denominator reduced by 10 points*
Population health measure (MIPS eligible clinician chooses one)	5/10 points	5/10 points
Quality Performance Category Achievement Percentage Score, Without Small Practice Bonus	33/50=0.66	28/40=0.70
Small Practice Bonus	(33+6)/50=0.78	(28+6)/40=0.85
Improvement Scoring 0-10%	2 percentage points added to 0.78=0.80	2 percentage points added to 0.85=0.87
Total Quality Performance Category Score	0.8 or 80%	0.87 or 87%

(ii) Scoring the Cost Performance Category in MVPs

We propose to use the methodology established for traditional MIPS to score the cost performance category for MVPs, including the proposed revisions to that methodology described in section IV.A.3.e.(1)(d) of this proposed rule. We refer readers to § 414.1380(b)(2)(i) through (v) for our policies to score the cost performance category for traditional MIPS based on achievement and improvement when the case minimum specified under § 414.1350(c) is met or exceeded and CMS has determined a benchmark. We propose at § 414.1365(d)(3)(ii) that the cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report.

Although we expect MVP Participants will submit MVPs that align clinically with their practice, we are concerned clinicians could use the reporting of MVPs to avoid being measured on clinically appropriate cost measures. For example, we are concerned larger groups could attempt to have the cost performance category reweighted by splitting into smaller subgroups that might not meet the case minimums for the cost measures within the MVP they choose to report. We intend to monitor the reporting of MVPs to ensure the use of MVPs reflects the clinical nature of the MVP Participants that report.

We request public comments on this proposal.

(iii) Scoring the Improvement Activities Performance Category in MVPs

Under traditional MIPS, we scored improvement activities by assigning each improvement activity a weight, either high-weight or medium-weight, and by assigning 10 points for each medium-weighted improvement activity and 20 points for each high-weighted improvement activity. We refer readers to § 414.1380(b)(3) for details on scoring the improvement activities performance category for traditional MIPS. Additionally, we refer the reader to §§ 414.1317(b)(3) and 414.1380, which indicates that MIPS eligible clinicians participating in APMs receive a score of at least 50 percent in the improvement activities performance category. As a result, APM entities that report an MVP will receive an improvement activities performance category score of at least 50 percent.

We believe we should continue scoring high-weighted and medium-weighted improvement activities that support the linked activities and measures specified within the MVP using a similar scoring methodology. However, for MVPs, we are proposing to assign 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity to align with the reporting requirements proposed in section IV.A.3.b.(4)(d)(iv) of this proposed rule, that require that MVP Participants report on one high weighted improvement or two medium weighted improvement activities. We believe that this would help to incentivize clinicians to report on MVPs versus traditional MIPs by reducing reporting burden, since fewer submissions are required to receive a full score.

Therefore, we propose at § 414.1365(d)(3)(iii) that the improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. We are also proposing that MVP Participants would receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii). Therefore, to receive a score of 40 points, or full credit, an MVP Participant must submit one high-weighted improvement activity or two medium-weighted improvement activities included in the MVP.

We request public comments on this proposal.

(iv) Scoring the Promoting Interoperability Performance Category in MVPs

We propose to use the scoring methodology established for the Promoting Interoperability performance category in traditional MIPS, and as proposed to be revised in section IV.A.3.d.(4) of this proposed rule, for MVP Participants, except for subgroups who would be scored based on their

affiliated group's Promoting Interoperability performance category data. The Promoting Interoperability performance category is a foundational layer of MVPs that uses limited, connected complementary sets of measures that are meaningful to clinicians. The scoring methodology for the Promoting Interoperability performance category recognizes the importance of promoting adoption and use of CEHRT to support quality improvement, interoperability, and patient engagement and provides an important approach to scoring that we propose to use for MVPs. We propose at § 414.1365(d)(3)(iv) to calculate the Promoting Interoperability performance category score for an MVP Participant using the methodology at § 414.1380(b)(4), except as provided at § 414.1365(d)(3)(iv)(A).

As discussed in section IV.A.3.b.(4), we proposed at § 414.1365(c)(4)(i)(A) to require subgroups to submit their affiliated group's data for the Promoting Interoperability performance category. We propose at § 414.1365(d)(3)(iv)(A) that if a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

We request public comments on these proposals.

(v) Facility-Based Scoring

We believe facility-based MIPS eligible clinicians and groups should have the same opportunities to submit MVPs as other MIPS eligible clinicians and groups. Please refer to 83 FR 59856 through 59865, regulation text at § 414.1380(e), and section IV.A.3.e.(2)(b)(v) of this proposed rule for our finalized and proposed policies for facility-based scoring. We propose at § 414.1365(e)(3) if an MVP Participant, that is not an APM Entity, is eligible for facility-based scoring, a facility-based score will also be calculated in accordance with § 414.1380(e). In this case, we would use the highest final score as proposed in section IV.A.3.e.(2)(b)(v) of this proposed rule and at § 414.1380(e)(6)(vi).

(c) Calculating the Final Score in MVPs

(i) Final Score Calculation

We propose at § 414.1365(e) that the final score is calculated for an MVP Participant using the same scoring methodology at § 414.1380(c) unless otherwise indicated in § 414.1365(e). This includes what is established for traditional MIPS, including proposed updates section IV.A.3.e.(2) of this proposed rule.

We request public comment on the proposal.

(A) General Performance Category Weights

We propose at § 414.1365(e)(1) to use the performance category weights established for traditional MIPS and described at § 414.1380(c)(1) to calculate the final score for an MVP Participant that is not an APM Entity. We also propose at § 414.1365(e)(1) to use the performance category weights established for APM Entities and described at § 414.1317(b) to calculate the final score for an MVP Participant that is an APM Entity. We refer readers to section IV.A.3.d.(5)(c) of this proposed rule where we propose additions to the regulation text at § 414.1317(b)(2).

We request public comments on these proposals.

(B) Flexibility for Weighting Performance Categories

(aa) Reweighting Performance Categories for MVPs

For MVP Participants, we are proposing reweighting policies that generally align with our current policies for traditional MIPS with a few minor modifications. We propose at § 414.1365(e)(2)(i) that for an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in the circumstances described at § 414.1380(c)(2)(i)(A)(2) through (9), and § 414.1380(c)(2)(i)(C). We also propose at § 414.1365(e)(2)(i) that for an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b) (see section IV.A.3.d.(5)(c) of this proposed rule for further information on proposed additions to the regulation text at § 414.1317(b)(2)).

As discussed in section IV.A.3.b.(5)(b)(i) of this proposed rule, for MVP Participants, we do not believe there will be cases where no measures in the quality performance category are available and applicable and can be scored. Therefore, we do not believe the traditional MIPS policy for reweighting the quality performance category as specified at § 414.1380(c)(2)(i)(A)(1) should be applicable to MVP Participants. We believe MVP Participants should select an MVP with four quality measures which can be scored based on achievement (unless clinicians report the Medicare Part B collection type and fewer than four measures are included in the MVP for that reporting option). We do not believe we should reweight the quality performance category if no quality measures in the MVP can be scored.

We propose at § 414.1365(e)(2)(ii) that for an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, we propose at § 414.1365(e)(2)(ii) that if reweighting is not applied to the affiliated group, the subgroup may receive reweighting independent of the affiliated group in the following circumstances. We believe a subgroup may be subject to extreme and uncontrollable circumstances that do not impact the entire affiliated group. For example, a subgroup might represent a single practice location that is affected by a natural disaster, while the affiliated group's other practice locations are not affected. Accordingly, we propose at § 414.1365(e)(2)(ii)(A) that a subgroup may submit an application to CMS demonstrating that it was subject to extreme and uncontrollable circumstances and receive reweighting in accordance with § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*). Under this proposal, we propose that in the event that a subgroup submits data for a performance category, the scoring weight described at § 414.1380(c)(1) would be applied and its weight would not be redistributed.

We are also concerned that subgroups, independent of their affiliated groups, may be subject to data that are inaccurate, unusable or otherwise compromised. We propose to add at § 414.1365(e)(2)(ii)(B) that, a subgroup will receive reweighting if CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for the subgroup are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the subgroup and its agents, in accordance with § 414.1380(c)(2)(i)(A)(*9*) and (c)(2)(i)(C)(*10*).

We request public comments on these proposals.

(C) Redistributing Performance Category Weights

We propose to redistribute the performance category weights for MVPs in accordance with the redistribution policies we propose for traditional MIPS in section IV.A.3.e.(2)(b)(iii) of this proposed rule. We propose at

§ 414.1365(e)(2)(iii) that for an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in accordance with § 414.1380(c)(2)(ii). We also propose at § 414.1365(e)(2)(iii) that for an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b) (see section IV.A.3.d.(5)(c) of this proposed rule for further information on proposed additions to the regulation text at § 414.1317(b)(2)).

We request public comments on this proposal.

(D) Complex Patient Bonus

We refer the reader to § 414.1380(c)(3) and section IV.A.3.e.(2)(a) of this proposed rule for our previously established and proposed policies on applying a complex patient bonus. We propose at § 414.1365(e)(4) to add a complex patient bonus to the final score for an MVP Participant in accordance with § 414.1380(c)(3).

We request public comments on these proposals.

(E) Scoring Example

Table 38 includes an example of calculation of the final score for MVPs. The example continues the example #1 from the quality scoring example in Table 37.

We note that the small practice bonus may constitute a larger proportion of the quality performance category score as compared with MIPS eligible clinicians reporting under traditional MIPS with a quality performance category denominator of 60 points, where the small practice bonus would add 10 percent to the quality performance category score. In cases where the quality performance category denominator is 50 points, as a result of 4 quality measures and one population health measure, a small practice bonus of 6 points would add 12 percent to the quality performance category score. We note that within traditional MIPS the quality performance category denominator can sometimes be less than 60 points (in cases where there are not 6 quality measures are relevant to the MIPS clinician, for example), and therefore, the small practice bonus is sometimes greater than 10 percent. We believe this variability is appropriate and believe that modifying the value of the small practice bonus for MVPs would cause unnecessary confusion.

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TABLE 38: Example MVP to Demonstrate Proposed Final Score Calculation

Quality Performance Category	Improvement Activities Performance Category	Cost Performance Category
Group receives a score of 80%, or 24/30 points in the final score (see Table 37 for quality category scoring). This includes 4 required measures and population health measures. *Subgroup score is unique to subgroup*	Group attests to 2 medium weighted activities, receives 40 performance category points and 15 points toward the final score *Subgroup score is unique to subgroup*	Group meets case minimum for 1 of 2 cost measures included in the MVP. Score 22 of 30 points in the final score *Subgroup score is unique to subgroup*
Foundational Layer (MVP agnostic) **Population Health Measures** Group selects population health measure A, case minimum is met and measure is included in the quality category score. *Subgroup score is unique to subgroup* **Promoting Interoperability (PI) Performance Category** Group scores 20/25 points on Promoting Interoperability performance category in the final score *Subgroup submits and is scored on the affiliated group's Promoting Interoperability performance category data*		
Final Score: **Quality Performance Category Score (24 points) +** **Improvement Activities Performance Category Score (15 points) +** **Cost Performance Category Score (22 points) +** **Promoting Interoperability Performance Category Score (20 points) +** **Complex Patient Bonus (4 points)** **= Final Score 85 points**		

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(d) Enhanced Performance Feedback in MVPs

(i) Background

In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that under section 1848(q)(12)(A)(i) of the Act, on an annual basis, we will provide confidential feedback to MIPS eligible clinicians and groups on their performance. Currently, in traditional MIPS, clinicians are not required to submit data throughout the performance period. Instead, data is submitted through the submission period that follows the performance period, as described at § 414.1325(e). In addition, current performance feedback includes measure-level performance data and scores, activity-level scores, and category comparison.

In the CY 2020 PFS final rule, we indicated a commitment to the transformation of MIPS to allow for streamlined, cohesive reporting through MVPs that would result in enhanced and timely feedback (84 FR 62945). Through previous rulemaking cycles, we have heard from stakeholders that clinicians are interested in receiving feedback reports from CMS throughout the year rather than annually to allow clinicians to review and make improvements where appropriate. Other stakeholders have expressed interest in receiving feedback which includes comparative data to other practices of similar size, location, and specialty. Stakeholders have indicated this is also key to put performance in perspective, particularly if performance evaluation and payment adjustments are contingent on the performance of other clinicians (84 FR 63057 through 63058).

(ii) Proposed Enhanced Performance Feedback in MVPs

A goal of enhanced performance feedback would be to compare similar clinicians to one another. For example, we could compare clinicians within a group or subgroup that practice in similar ways. We considered two options for providing enhanced performance feedback. The first option is to provide comparative performance feedback, comparing the performance of like clinicians who report on the same MVP, which provides more granular comparison than the current performance feedback under traditional MIPS. This method does not require clinicians to submit data earlier than they currently do. In addition, we anticipate that we could provide comparative performance feedback at the time of annual performance feedback. The second option is to provide performance feedback during the performance period. We acknowledge stakeholders would like to receive more timely and actionable feedback during the performance period. However, there are complexities that need mitigation to pursue this option. These complexities include requiring clinicians to submit data earlier to provide enhanced performance feedback during the performance period, and requiring a significant investment of resources, including both time and money for CMS, third party intermediaries, and clinicians.

Therefore, beginning with the CY 2023 performance period, we propose the first option described—to include comparative performance feedback within the annual performance feedback we provide for MVP Participants, comparing the performance of similar clinicians who report on the same MVP. The comparative feedback would only be available to those who report on MVPs, and would be incorporated into the annual performance feedback that we currently provide in traditional MIPS.

We request public comments on this proposal.

(iii) Request for Information for Future Consideration

As described in the CY 2020 PFS proposed rule (84 FFR 40733 through 40734), stakeholders have requested that they be provided with actionable feedback. To gain a better understanding, we request comments from stakeholders to elaborate on what they consider to be ''actionable''. Would this include CMS identifying in the annual performance feedback areas of improvement based on how a clinician scores on a measure? Is there unintended burden to stakeholders such as third party intermediaries and EHR vendors associated with receiving ''actionable'' feedback? For example, this could include financial burden from system changes or operational burden on changes to workflows.

We request public comments on the above.

b. APM Performance Pathway

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859), we finalized the APM Performance Pathway (APP), which was designed to provide a predictable and consistent MIPS reporting option to reduce reporting burden and encourage continued APM participation. The APP is available for reporting by any submitter type, with the exception of Virtual Groups.

(2) MIPS Performance Category Scoring

(a) Quality Performance Category

In the CY 2021 PFS final rule, we finalized our proposal to use the measures listed in Table 39 for purposes of quality performance category scoring for the APP.

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TABLE 39: Measures included in the Final APM Performance Pathway Measure Set+

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

+ We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

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In the CY 2021 PFS final rule, we finalized the inclusion of the CMS Web Interface as an option for Shared Savings Program ACOs to report quality for the 2021 performance period only, with such quality reporting option no longer available beginning with the CY 2022 performance period. However, since the CY 2021 PFS final rule, we have received stakeholder feedback that the transition away from reporting the CMS Web Interface measures to the reporting of eCQMs/MIPS CQMs is more technologically difficult for some ACOs than originally anticipated, particularly under the extraordinary circumstances of the PHE for COVID–19. In light of this feedback, we are proposing to extend the CMS Web Interface as a means of reporting quality under the APP for Shared Savings Program ACOs for performance years 2022 and 2023.

Under this proposal, for performance year 2022, Web Interface reporting would work in the same manner as for performance year 2021, where ACOs would have the option of reporting either the CMS Web Interface, the APP eCQM/MIPS CQM measure set, or both.

In addition, we are proposing that for the 2023 performance year, we would only score Web Interface submissions for ACOs that have also submitted at least one eCQM/MIPS CQM measure from the APP measure set. While we understand that there may be barriers to ACOs transitioning away from the CMS Web Interface along the timeline

originally contemplated, we believe it is important to continue to encourage and incent that transition. By extending the CMS Web Interface for the 2022 and 2023 performance years, as proposed, we would give ACOs additional time to familiarize themselves with the eCQM/MIPS CQM measures and the data aggregation and submission processes. However, we believe that by also proposing to limit the continued use of the CMS Web Interface in the 2023 performance year only to those ACOs that also attempt an eCQM/MIPS CQM submission, we would continue to move these ACOs and their ACO participants towards CMS' goal of more complete and uniform reporting requirements for all MIPS participants.

We note that for both performance year 2022 and performance year 2023, ACOs would continue to have the opportunity to report on both the eCQMs/MIPS CQMs and the CMS Web Interface measures, and to have their MIPS quality performance category score based on the higher submission. We believe these proposed policies will help to encourage ACOs to move towards eCQM/MIPS CQM reporting in a low-risk environment where they will have the opportunity to continue to rely on measures reported through the CMS Web Interface for purposes of quality performance scoring as they become familiar with the eCQM/MIPS CQM submission and scoring process.

We seek comment on these proposals.

For the CY 2021 MIPS performance period, we limited the use of the Risk-standardized, All-cause Unplanned Admissions for Multiple Chronic Conditions for ACOs (MCC for ACOs) measure to ACOs because, at that time, we were still investigating the question of whether it would be appropriate to include the Risk-standardized, All-cause Unplanned Admissions of Multiple Chronic Conditions for MIPS (MCC for MIPS) measure in the generally applicable MIPS quality measure set. However, we are proposing to add the MCC for MIPS measure into the MIPS quality measure set beginning with the CY 2022 MIPS performance period, as discussed in Appendix 1 of this proposed rule.

We are also proposing to replace the MCC for ACOs measure with the MCC for MIPS measure within the APP beginning with the 2022 MIPS performance period. This change would continue our transition towards alignment of quality measure data reported by MIPS eligible clinicians who are not participants in APMs and those who are, as discussed in the CY 2021 PFS final rule (85 FR 84859). We believe the MCC for MIPS measure is a valuable tool in assessing quality performance, with no additional reporting burden, and is therefore an asset to the APP measure set as well. By replacing the MCC for ACOs measure with the MCC for MIPS measure, we would have the opportunity to capture performance on this measure for additional MIPS eligible clinicians who are not participants in ACO-based APMs.

We also believe it is important to remove the MCC for ACOs measure from the APP in order to reduce the potential for confusion around performance scores and feedback for MIPS eligible clinicians who might otherwise have been scored on both measures with differing results.

We seek comment on our proposal to include the measures listed in Table 40 in the quality measure set for the APP for the 2022 MIPS performance period.

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TABLE 40: Measures included in the Proposed APM Performance Pathway Measure Set[202]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for MIPS	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

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d. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to §§ 414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In this proposed rule, we propose to:

- Maintain the data completeness criteria threshold of at least 70 percent for 2021 and 2022 MIPS performance periods (2023 and 2024 MIPS payment years), and increase the data completeness criteria threshold to at least 80 percent for the 2023 MIPS performance period (2025 MIPS payment year).
- Extend the availability of the CMS Web Interface as a collection and submission type for the 2022 MIPS performance period.
- Make changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, including addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.
- Establish criteria for determining whether a measure change is considered substantive starting with 2022 MIPS performance period.

[202] We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Quality ID# 236) do not have benchmarks and are therefore not scored for PY 2022; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2022 & 2023 MIPS performance periods only.

• Beginning with the 2021 MIPS performance period CAHPS for MIPS survey, Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) are required to administer the CAHPS for MIPS Survey and report via the Alternative Payment Model (APM) Performance Pathway (APP). We are proposing refinements to our policies for administration of the CAHPS for MIPS survey to align with certain policies that previously applied to the CAHPS for ACOs survey.

(b) Data Submission Criteria

(i) Submission Criteria for Quality Measures Excluding the CMS Web Interface and CAHPS for MIPS

In the CY 2017 QPP final rule, we established the submission criteria for quality measures (excluding the CMS Web Interface measures and the CAHPS for MIPS survey measure) at § 414.1335, which requires a MIPS eligible clinician, group, or virtual group that is reporting on Qualified Clinical Data Registry (QCDR) measures, MIPS clinical quality measures (MIPS CQMs), electronic CQMs (eCQMs), or Medicare Part B claims measures to submit data on at least 6 measures, including at least 1 outcome measure (81 FR 77100 through 77114). If an applicable outcome measure is not available, then a MIPS individual eligible clinician, group, or virtual group would report on 1 other high priority measure. If there are fewer than 6 measures that apply to a MIPS eligible clinician, group, or virtual group, then reporting on each applicable measure is required. For MIPS eligible clinicians, groups, and virtual groups that report on a specialty or subspecialty measure set (as designated in the MIPS final list of quality measures established by CMS through rulemaking), they are required to submit data on at least 6 measures within the set, including at least 1 outcome measure. If an applicable outcome measure is not available, then a MIPS individual eligible clinician, group, or virtual group would report on 1 other high priority measure. If a specialty or subspecialty measure set contains fewer than 6 measures or if fewer than 6 measures within the measure set apply to a MIPS eligible clinician, group, or virtual group, then reporting on each applicable measure is required. In addition to the assessment of performance based on submitted data for at least 6 measures (all measures if there are fewer than 6 measures that are applicable), performance is also assessed on administrative claims measures. CMS automatically evaluates and calculates administrative claims measures for individual MIPS eligible clinicians, groups, and virtual groups if the case minimum requirement of the measure is met.

With each year of program implementation, we continue to assess means for creating a more cohesive and meaningful participation experience in MIPS that improves value and reduces clinician burden. As the program evolves, we want to enable a seamless transition from participation in traditional MIPS to the preliminary onset of voluntary participation in MVPs to the required participation in MVPs. Transitioning from traditional MIPS to MVPs improves the participation experience of MIPS by having the program be more relevant to a clinician's scope of practice and meaningful to patient care. One element that we assessed in preparation for the transition from traditional MIPS to MVPs regards the utilization of outcomes-based administrative claims measures to reduce the reporting burden under MIPS, particularly the allowance of outcome-based administrative claims measures to be applied as the required outcome measure requirement under traditional MIPS (in general, 6 measures, including 1 outcome measure) and MVPs (in general, 4 measures as outlined in section IV.A.3.b.(4)(d)(ii) of this proposed rule).

Since the inception of MIPS under the Quality Payment Program starting with the 2017 MIPS performance period, we established administrative claims measures that are automatically evaluated and calculated for individual MIPS eligible clinicians, groups, and virtual groups if the case minimum requirement of the measure is met (81 FR 77130 through 77136). With CMS conducting the assessment and calculations of administrative claims measures, the reporting burden for individual MIPS eligible clinicians, groups, and virtual groups is reduced (81 FR 77134). A subset of the administrative claims measures are outcome-based measures (and in some cases, are also population health measures), which focus on the improvement of patient health outcomes. As more outcome-based administrative claims measures are implemented in MIPS, we would like to further reduce the reporting burden by allowing such measures (not applicable to administrative claims measures that are considered population health measures) to fulfill the outcome measure requirement, when applicable. For the 2022 MIPS performance period, we are proposing the following outcome-based administrative claims measure under MIPS: Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System (see Table Group A of Appendix 1 of this proposed rule).

In section IV.A.3.b.(4)(d)(ii) of this proposed rule, we are proposing at § 414.1365(c)(1) to allow an administrative claims measure that is outcome-based (not applicable to administrative claims measures that are population health measures), if applicable, to be selected at the time of MVP registration as a measure to meet the outcome measure requirement starting with the 2023 MIPS performance period. The outcomes-based administrative claims measure would be applicable and relevant to the specific MVP, and as a result, included as 1 of the measures available within an MVP. Once an outcomes-based administrative claims measure is selected during the MVP registration process, the measure would meet the outcome-based measure reporting requirement and count as 1 of the 4 minimum required measures if the MVP Participants meet the case minimum requirement for the administrative claims measure; otherwise, the administrative claims measure would receive a score of zero points and the MVP Participants would not meet the minimum reporting requirement of 4 measures. However, if the MVP Participants select an outcomes-based administrative claims measure available within the MVP and report on 4 measures, the MVP Participants would meet the minimum reporting requirement of 4 measures if it was determined that the case minimum requirement for the outcomes-based administrative claims measure was not met. We believe that such approach reduces reporting burden and allows for a more cohesive and meaningful participation experience that focuses on measures that are more relevant to a clinician's scope of practice while preventing gaming/misuse of selecting an outcomes-based administrative claims measures to be assessed and scored on for purposes of MVP participation.

As we analyzed the allowance and utilization of outcome-based administrative claims measures (not applicable to administrative claims measures that are population health measures) to be applied to fulfill the outcome measure requirement within traditional MIPS, it became apparent that the implementation of such a policy would pose challenges and obstacles. We assessed 3 options. For the first

option, we assessed the potential implementation of outcomes-based administrative claims measures to fulfill the outcome requirement utilizing a registration system, similar to the proposal for MVPs. For traditional MIPS, a registration process would require the individual MIPS eligible clinicians, groups, and virtual groups to elect to have an outcomes-based administrative claims measure be calculated and scored to fulfill the outcome measure requirement as part of the 6 minimum required measures. Prior to an individual MIPS eligible clinician, group, or virtual group making such an election via a registration process, it would be imperative for a registration process to only permit an individual MIPS eligible clinician, group, or virtual group to register if eligible (meets case minimum requirement) for an outcome-based administrative claims measure (not applicable to administrative claims measures that are population health measures) to be calculated and scored. Such registration process would need to be able to identify which individual MIPS eligible clinicians, groups, and virtual groups would be eligible for an outcome-based administrative claims measure to fulfill the outcome measure requirement as part of the required minimum of 6 measures, which would prevent the potential for gaming and enable individual MIPS eligible clinicians, groups, and virtual groups to know in advance of the submission period if they would need to report on a minimum of 5 measures instead of a minimum of 6 measures; we believe that this approach would reduce burden.

In addition, for cases in which the case minimum of the outcomes-based administrative claims measure would not be met and therefore, could not be calculated, we have considered whether the denominator should be reduced and performance assessment and scoring would be based on 5 measures instead of 6 measures (or less measures if, initially, there were fewer than 6 applicable measures or fewer than 6 measures available within a measure set), which would reduce the reporting burden under traditional MIPS. However, we recognize that if our policy—an election process, via a registration system, to have an outcome-based administrative claims measure as 1 of the required minimum of 6 measures—includes an element for a denominator reduction, we believe that our policy would pose the potential risk for gaming. We would want to prevent the potential for gaming—knowingly selecting an outcome-based administrative claims measures during registration that is not applicable to a practice or specialty, which would result in not meeting the case minimum requirement to be calculated and scored on such measure, and thus, having performance assessed on 5 measures instead of 6 measures (or less measures if, initially, there were fewer than 6 applicable measures or fewer than 6 measures available within a measure set).

As we assessed such approach, we believed that there would not be sufficient parameters/safeguards to ensure that only individual MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure calculation would be able to register. We would seek to prevent the potential for gaming by minimizing the number of individual MIPS eligible clinicians, groups, and virtual groups not eligible for an outcome-based administrative claims measure calculation to make such election. However, as we conducted our assessment, we determined that it would not be technically possible to develop a registration system based on applicable outcomes based administrative claims measure data for the applicable performance period to identify if a MIPS eligible clinician, group, or virtual group is eligible for an outcome-based administrative claims measure calculation given that such data would not be readily available until several months after the end of an applicable MIPS performance period. Without having an ability to identify MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure calculation for registration purposes based on data from the applicable performance period in order to prevent gaming, we believed that the implementation of a policy to allow for an outcome-based administrative claims measure to be applied as 1 of the minimum required 6 measures would pose risk to the integrity of the program. For the second option, we assessed the potential for automatically calculating an outcome-based administrative claims measure, if applicable, for individual MIPS eligible clinicians, groups, and virtual groups participating in traditional MIPS. For the implementation of such a policy, we would use the status quo of requiring the submission of the minimum of 6 measures (or less measures if fewer than 6 measures were applicable or fewer than 6 measures were available within a measure set) (81 FR 77100 through 77114) in addition to automatically calculating an applicable outcome-based administrative claims measure. We would calculate a score for a total of 7 measures (6 required measures and outcome-based administrative claims measure), but performance for the quality performance category would be based on 6 measures with the highest score, which would include an outcome-based measure.

For option 2, we would not be reducing the reporting burden given that the reporting requirements would remain as status quo, but instead of us applying all administrative claims to all MIPS eligible clinicians as an addition to their quality performance category denominator, we would be replacing the outcome measure requirement, with an available outcomes-based administrative claims measure, if it can be applied. Under this approach, we would not be able to objectively decipher the intent of a MIPS eligible clinician, group, or virtual group (without a formal process to signify an election) as to whether or not they would want to have the outcome-based administrative claims measure automatically calculated and applied as 1 of the 6 minimum required measures. To not objectively know the intension of a MIPS eligible clinician, group, or virtual group, the following scenario could arise under option 2. For example, a MIPS eligible clinician, group, or virtual group submitted 5 measures, it is unclear if it was intentional to only submit 5 measures with the expectation that the MIPS eligible clinician, group, or virtual group sought to be evaluated on the outcomes-based administrative claims measure or if the submission of 5 measures was a result of a MIPS eligible clinician, group, or virtual group of not meeting the minimum of 6 required measures and thus, receive zero points for 1 of the 6 required measures.

After assessing the first 2 aforementioned options, we assessed a third option that would address concerns regarding the first 2 options. For option 3, we assessed the utilization of historical data (for example, previous MIPS performance period data) given that applicable performance period data would not be readily available to be included as part of a registration process. The use of historical data for an outcome-based administrative claims measure as the means for eligibility determinations within a registration system would only permit individual MIPS eligible clinicians, groups, and virtual groups identified as eligible for the calculation of an outcome-based administrative claims measure. Such option would allow an individual MIPS eligible clinician, group, or virtual

group to select the application of an outcome-based administrative claims measure during a registration process, which would allow CMS to identify the individual MIPS eligible clinicians, groups, and virtual groups electing to have such measure applied as 1 of the minimum-required 6 measures that meets the outcome-based measure requirement. We believe that historical data would be able to adequately and reliably identify individual MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure calculation, which we anticipate could be available during the applicable MIPS performance period, as technically feasible. We believe that by providing this historical information to individual MIPS eligible clinicians, groups, and virtual groups would provide pertinent information to make a determine if they would be selecting an outcome-based administrative claims measure during a registration process to be applied as 1 of the minimum-required 6 measures. We believe this approach could minimize gaming and individual MIPS eligible clinicians, groups, and virtual groups would know that they would need to select a minimum of 5 (instead of 6) other measures to meet the reporting requirements for the quality performance category. The potential drawback to this option is it would only be available for individual MIPS eligible clinicians, groups, and virtual groups who participated in MIPS for a prior performance period, so not all clinicians would benefit under this option. However, if technically feasible, the utilization of historical data from the outcome-based administrative claims measure would be able to reduce the reporting burden and would align with the similar proposed process for MVPs. Although we are not making a proposal for the implementation of such policy, we would like to obtain feedback from stakeholders regarding how the automatic calculation of an outcome-based administrative claims measure and have it applied as 1 of the minimum 6 required measures, particularly the outcome-based measure requirement, and if such option is a policy that would be advantage for them as they participate in traditional MIPS. We actively seek the engagement of our stakeholders as we assess means for reducing the reporting burden and enhance the experience of participating in traditional MIPS.

Thus, we are seeking public comment on the means for being able to implement such a policy. Are there other options that we should consider in determining how to implement such a policy? Are there other ways we would be able to identify which individual MIPS eligible clinicians, groups, and virtual groups are eligible for an outcomes-based administrative measure calculation to ensure that only those that are eligible are able make such an election? Should we consider the use of historical data that would allow the predetermination and identification of MIPS eligible clinicians, groups, and virtual groups eligible for an outcome-based administrative claims measure? How would we be able to determine if a MIPS eligible clinician, group, or virtual group would like to have an automatic calculation of an outcome-based administrative claims measure conducted on their behalf outside of a registration process? Are there other challenges that we should be aware of as we continue to assess a means for developing and implementing such a policy?

(c) Data Completeness Criteria

(i) 2021 MIPS Performance Period (2023 MIPS Payment Year)

In the CY 2020 PFS final rule, we established the data completeness criteria at § 414.1340(a)(3) and § 414.1340(b)(3) for the 2020 MIPS performance period (2022 MIPS payment year), which determined that MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs, or Medicare Part B claims measures must submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer. In regard to the data completeness criteria established for Medicare Part B claims measures for the 2020 MIPS performance period (2022 MIPS payment year), we found that the policy established at § 414.1340(b)(3) erroneously reflected the data completeness criteria only applicable to QCDR measures, MIPS CQMs, and eCQMs, which requires data submission to pertain to patients that meet the measure's denominator criteria, regardless of payer (all-payer). It is not possible for Medicare Part B claims data to include all-payer patients; the submission of data for Medicare Part B claims measures can only account for Medicare Part B patients. Since the implementation of MIPS, the data completeness criteria for Medicare Part B claims measures has pertained to the applicable Medicare Part B patients seen during an applicable MIPS performance period. The issue with the policy established at § 414.1340(b)(3) in the CY 2020 PFS final rule for Medicare Part B claims measures only pertains to the type of patient population for data submission purposes and not the threshold established for data completeness of at least 70 percent. Thus, we are proposing to modify the data completeness threshold criteria established at § 414.1340(b)(3) for the 2020 MIPS performance period (2022 MIPS payment year) retroactively, effective January 1, 2020, in accordance with section 1871(e)(1)(A)(ii) of the Act. We believe that failure to apply the change retroactively would be contrary to the public interest because it would require individual eligible clinicians, groups, and virtual groups to meet data completeness criteria (the submission of patient data for all-payers) for Medicare Part B claims measures that is not possible. We believe that it is imperative for individual eligible clinicians, groups, and virtual groups to be certain as to the true criteria used to measure data completeness for Medicare Part B claims measures. For the 2021 MIPS performance period (2023 MIPS payment year), we are proposing to modify the data completeness criteria established at § 414.1340(b)(3) to be as follows: MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2022.

In the CY 2021 PFS proposed and final rules, we inadvertently omitted a proposal that would have otherwise extended our existing policy to determine the data completeness criteria for the 2021 MIPS performance period (2023 MIPS payment year); we only included a reference to the data completeness criteria of at least 70 percent for the 2021 MIPS performance period (2023 MIPS payment year) as it relates to the scoring policies for class 1 measures as outlined in Table 49 of the CY 2021 PFS proposed and final rules (85 FR 50309 and 85 FR 84906). Thus, we are proposing to establish the data completeness criteria for the 2021 MIPS performance period (2023 MIPS payment year) retroactively, effective January 1, 2021, in accordance with section 1871(e)(1)(A)(ii) of the Act. We believe that failure to apply the change retroactively would be contrary to the public interest because it could be construed as permitting the submission of incomplete, inaccurate, or otherwise comprised data, which would have a detrimental effect on the performance data used for calculating MIPS payment

adjustments and public reporting. For the 2021 MIPS performance period (2023 MIPS payment year), we are proposing: At § 414.1340(a)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs would need to submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer; and at § 414.1340(b)(3) to establish the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the 2021 MIPS performance period to which the measure applies for MIPS payment year 2023.

We believe that it is imperative to establish the data completeness criteria for the 2023 MIPS payment year in this proposed rule and any failure to apply the updated data completeness criteria retroactively would be contrary to the public interest as such omission presents ambiguity and a potential notion for an array of interpretations. We believe that it is in the public interest to retroactively apply the updated data completeness threshold as it would ensure that all MIPS eligible clinicians participating in MIPS for the 2021 MIPS performance period (2023 MIPS payment year), whether at the individual, group, or virtual group levels, would be aware that there is a definitive data completeness criteria for the 2021 MIPS performance period and any data submitted for the quality performance category would need to meet the data completeness criteria. We believe that such approach would: Establish the data completeness criteria prior to the timeframe in which data submission would occur (first 3 months of CY 2022), which would enable MIPS eligible clinicians participating in MIPS at the individual, group, or virtual group levels to prepare their data submission to meet the updated data completeness criteria; and ensure that all data submitted for the quality performance category would meet the same criteria (that is, specific data completeness threshold of at least 70 percent of a MIPS eligible clinician or group's patient population that meets the measure's denominator criteria for QCDR measures, MIPS CQMs, and eCQMs; or specific data completeness threshold of at least 70 percent of the applicable Medicare Part B patients seen during the 2021 MIPS performance period for Medicare Part B claims measures) versus an unspecified, interpretive data completeness threshold that could result in various threshold ranges and inconsistent reported patient populations such as portion of submitted data be a representative of all patient (all-payer) data while the remaining portion of submitted data be a representative of only Medicare patient data, which would provide data integrity, usability, and reliability to assess the performance of MIPS eligible clinicians at the individual, group, or virtual group level in a manner that is consistent and enable performance data to be comparable to the applicable historical benchmarks that have been established for the various measures.

(ii) 2022 MIPS Performance Period (2024 MIPS Payment Year)

In the CY 2017 and CY 2018 Quality Payment Program final rules, we note that we would increase the data completeness criteria threshold over time (81 FR 77121 and 82 FR 53632). Starting with the 2020 MIPS performance period (2022 MIPS payment year), we increased the data completeness criteria from at least 60 percent to at least 70 percent and as noted above, we are proposing to maintain the data completeness criteria threshold of at least 70 percent for the 2021 MIPS performance period (2023 MIPS payment year). We continue to believe that it is important to incrementally increase the data completeness criteria as MIPS eligible clinicians, groups, and virtual groups gain experience with MIPS. However, with the COVID–19 PHE that started during the 2020 MIPS performance period (2022 MIPS payment year) and continued into the 2021 MIPS performance period (2023 MIPS payment year), we believe that it would be appropriate to continue to maintain the data completeness criteria of at least 70 percent for the 2022 MIPS performance period (2024 MIPS payment year) as healthcare systems across the country have been overwhelmed and strained by the COVID–19 PHE.

In order to not place further undue burden as MIPS eligible clinicians, groups, and virtual groups navigate through the COVID–19 pandemic, we are proposing:

- At § 414.1340(a)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, or eCQMs would need to submit data on at least a 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer, for the 2022 MIPS performance period (2024 MIPS payment year); and
- At § 414.1340(b)(3) to maintain the data completeness criteria threshold of at least 70 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 70 percent of the applicable Medicare Part B patients seen during the 2022 MIPS performance period to which the measure applies for MIPS payment year 2024.

(iii) 2023 MIPS Performance Period (2025 MIPS Payment Year)

We believe that the incorporation of higher data completeness thresholds in future years ensure a more accurate assessment of a MIPS eligible clinician's performance on quality measures and avoid any selection bias. We have strongly encouraged all MIPS eligible clinicians to perform the quality actions associated with the quality measures on their patients. The data submitted for each measure is expected to be representative of the individual MIPS eligible clinician, group, or virtual group's overall performance for that measure. The data completeness threshold of less than 100 percent is intended to reduce burden and accommodate operational issues that may arise during data collection during the initial years of the program.

Since the inception of the program, we have provided notice to MIPS eligible clinicians, groups, and virtual groups in order for them to take the necessary steps to prepare for higher data completeness thresholds in future years. In a similar manner, we are providing advance notice that we intend to increase the data completeness criteria threshold for the 2023 MIPS performance period (2025 MIPS payment year). We are proposing: At § 414.1340(a)(4) to increase the data completeness criteria threshold from at least 70 percent to at least 80 percent, in which MIPS eligible clinicians and groups submitting quality measures data on QCDR measures, MIPS CQMs, eCQMs, or Medicare Part B claims measures would need to submit data on at least a 80 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer, for the 2023 MIPS performance period (2025 MIPS payment year); and at § 414.1340(b)(4) to increase the data completeness

criteria threshold from at least 70 percent to at least 80 percent, in which MIPS eligible clinicians and groups submitting quality measures data on Medicare Part B claims measures must submit data on at least 80 percent of the applicable Medicare Part B patients seen during the 2023 MIPS performance period to which the measure applies for MIPS payment year 2025. We believe that MIPS eligible clinicians, groups, and virtual groups would be provided with adequate time to prepare for the data completeness criteria threshold to increase.

We seek public comment on our proposals to maintain the data completeness criteria threshold of at least 70 percent for the 2021 and 2022 MIPS performance periods (2023 and 2024 MIPS payment years), and increase the data completeness criteria threshold from at least 70 percent to at least 80 percent for the 2023 MIPS performance period (2025 MIPS payment year).

(d) Groups and Virtual Groups Reporting via the CMS Web Interface

At § 414.1335(a)(2), the CMS Web Interface measures is a collection type in which groups and virtual groups with 25 or more eligible clinicians are able to report data on a set of pre-determined quality measures. For the 2021 MIPS performance period, the total number of CMS Web Interface measures required to complete reporting on is 10 CMS Web Interface measures (83 FR 59713 through 79715 and 59756). In the CY 2021 PFS final rule, at § 414.1325(c)(1) *et seq.,* the CMS Web Interface was sunset and removed as an available collection and submission type under MIPS starting with the 2022 MIPS performance period (85 FR 84870). In addition, starting with the 2022 MIPS performance period, the definition of the terms collection type and submission type would no longer include the CMS Web Interface measures as an available option. It was our belief that the sunset and removal of the CMS Web Interface as a collection and submission type starting with the 2022 MIPS performance period would reduce the potential burden experienced by groups and virtual groups during the COVID–19 PHE. Based on the public comments received during the notice-and-comment rulemaking process for the CY 2021 PFS proposed rule, we believed that the 1-year delay to sunset and remove the CMS Web Interface as a collection and submission type would provide stakeholders utilizing the CMS Web Interface sufficient time to prepare and transition to an alternative collection and/or submission type starting with the 2022 MIPS performance period.

However, following the close of the submission period for the 2020 MIPS performance period (March 31, 2021), stakeholders utilizing the CMS Web Interface contacted CMS to convey concerns regarding the technological challenges and resource limitations they face that would prevent them from being able to adequately transition to implementing and utilizing an alternative collection and/or submission type starting with the 2022 MIPS performance period. Also, they emphasized that some practices around the country continue to endure a fiscal impact resulting from the COVID–19 pandemic and would need additional time to prepare for a transition to an alternative collection and/or submission type. They indicated that if the availability of the CMS Web Interface was extended for an additional year (the 2022 MIPS performance period), they would have sufficient time to address technological challenges such as the implementation of processes to aggregate data within one EHR system or across multiple EHR systems to align with the reporting requirements of another collection type (that is, MIPS CQMs or eCQMs), build and integrate new health IT infrastructures and systems, implement workflows, and train staff on new health IT systems.

We recognize that an adequate and sufficient timeframe is a critical factor in the success of a group or virtual group transitioning to an alternative collection and/or submission type, particularly with such transition occurring amidst the mitigation of the COVID–19 pandemic. It seems that as CMS Web Interface users began the actualization of preparing and taking steps to transition to utilizing a different collection and/or submission type, the timeframe identified by most CMS Web Interface users (starting with the 2022 MIPS performance period) during the notice-and-comment rulemaking process for the CY 2021 PFS proposed rule, which is reflective of our policy to sunset the CMS Web Interface starting with the 2022 MIPS performance period, would not have provided an adequate or sufficient timeframe for CMS Web Interface users to fully transition to an alternative collection and/or submission type. In considering the concerns expressed by CMS Web Interface users such as the technological challenges that they would need to overcome, their inability to update systems and workflows in time for the 2022 MIPS performance period, and the fiscal implications they endure from mitigating and responding the COVID–19 PHE, we believe it is appropriate to reduce the burden of groups and virtual groups at this juncture and postpone the sunset of the CMS Web Interface by extending the availability of the CMS Web Interface as a collection and submission type for the 2022 MIPS performance period. We recognize that groups and virtual groups are on a continuum with regard to technological readiness for transitioning to a different collection type, but we believe that the availability of the CMS Web Interface for the 2022 MIPS performance period would reduce burden by providing additional time, and enable more groups and virtual groups to be able to successfully transition to another collection type by the start of the 2023 MIPS performance period. Moreover, we want to ensure that groups utilizing the CMS Web Interface are prepared to participate in MIPS as it evolves from traditional MIPS to MVPs, in which such groups could begin voluntary participation in an MVP as the availability of MVPs become an option starting with the 2023 MIPS performance period.

We are proposing at § 414.1325(c)(1) *et seq.* to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2023 performance period. Specifically, at § 414.1305, we are proposing to modify the definition of the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the CY 2022 MIPS performance period/2024 MIPS payment year. We are proposing to modify the definition of ''collection type'' to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the CY 2017 through 2022 MIPS performance periods/2019 through 2024 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS Survey; and administrative claims measures. We are proposing to modify the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the CY 2017 through 2022 MIPS performance periods/2019 through 2024 MIPS payment years, the CMS Web Interface.

For the 2022 MIPS performance period, the total number of CMS Web Interface measures required to complete reporting on would be 10 CMS Web

Interface measures (83 FR 59713 through 79715 and 59756). In Table Group B of Appendix 1 of this proposed rule, we are proposing modifications to the CMS Web Interface measures and in Table Group D of Appendix 1 of this proposed rule, we are proposing substantive changes to the CMS Web Interface measures. We believe that it is necessary for the CMS Web Interface measures to be updated to reflect applicable substantive changes for the 2022 MIPS performance period given that the CMS Web Interface measures have remained the same for 3 consecutive (2019, 2020, and 2021) MIPS performance periods.

We solicit public comment on our proposals: To extend the availability of the CMS Web Interface as a submission and collection type for the 2022 MIPS performance period, which would sunset and remove the collection and submission type under MIPS starting with the 2023 performance period; and update the CMS Web Interface measures with substantive changes for the 2022 MIPS performance period as outlined in Table Group B of Appendix 1 of this proposed rule.

(e) Selection of MIPS Quality Measures

Previously finalized MIPS quality measures can be found in the CY 2021 PFS final rule (85 FR 85045 through 85377); CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). Proposed changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, include the following: Addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the 2022 MIPS performance period, we are proposing a measure set of 195 MIPS quality measures.

The new MIPS quality measures proposed for inclusion in MIPS for the 2022 performance period and future years are found in Table Group A of Appendix 1 of this proposed rule. For the 2022 MIPS performance period, we are proposing 5 new MIPS quality measures, which includes 2 administrative claims measures. Also, in Table Group AA of Appendix 1, we outline 1 potential new MIPS quality measure, the COVID–19 Vaccination by Clinicians measure, which we intend to propose in a future rulemaking cycle. We refer readers to section IV.A.3.d.(1)(f) of this proposed rule for our request for information pertaining to the COVID–19 Vaccination by Clinicians measure specifications.

In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. Our proposals for modifications to existing specialty sets and new specialty sets are outlined in Table Group B of Appendix 1 of this proposed rule. Specialty sets may include: New measures, previously finalized measures with modifications, previously finalized measures with no modifications, the removal of certain previously finalized quality measures, or the addition of existing MIPS quality measures. Please note that the specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 7, 2021, we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 6 of MIPS under the Quality Payment Program.[203] These recommendations were based on the MIPS quality measures finalized in the CY 2020 PFS final rule, the 2020 Measures Under Consideration list, and provides recommendations to add or remove the current MIPS quality measures from existing specialty sets, or provides recommendations for the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are being proposed in this proposed rule.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for removal. For the 2022 MIPS performance period, we are proposing to remove 19 MIPS quality measures: 1 MIPS quality measure that is duplicative to another current MIPS quality measure; 9 MIPS quality measures that do not align with the Meaningful Measure Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; and 4 MIPS quality measures that are under the topped out lifecycle. We have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. We believe our proposal to remove the quality measures outlined in Table Group C will lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria.

Lastly, MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 of this proposed rule. We are proposing substantive changes to 84 MIPS quality measures. On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. In the CY 2017 Quality Payment Program final rule (81 FR 77137), we determined that substantive changes to measures (that is, measure specifications, measure title, and domain modifications) would be identified during the rulemaking process while maintenance changes that do not substantively change the intent of the measure (that is, updated diagnosis and procedure codes, definitions, and changes to patient population exclusions) would not be included in the rulemaking process.

We are not proposing any changes to our current approach of identifying substantive measures changes during the rulemaking process. However, in order to more precisely distinguish between substantive measure changes and non-substantive measure changes, we are proposing to consider the following criteria for determining whether a measure change is substantive starting with 2022 MIPS performance period:

- Whether the change causes the measure to be more stringent;
- Whether the change modifies the collection and/or submission types applicable to the measure;
- Whether the change impacts the clinical action and/or outcome of the measure;
- Whether the change increases the burden of the measure;
- Whether the change modifies the premise and/or objective of the measure;

[203] Listserv messaging was distributed through the Quality Payment Program listserv on January 7, 2021, entitled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2022 Program Year of MIPS.''

- Whether the change modifies the scope of the measure (such as patient population eligible for the measure or measurement period); and
- Other relevant criteria as may be identified by CMS on a case-by-case basis.

We note that any substantive change made to a measure would be proposed and identified through notice-and-comment rulemaking. For a substantive change to a measure, we only intend to propose and identify the substantive change as applicable to the appropriate elements (that is, only include substantive changes if it is applicable to the measure specifications, collection type(s), measure description, measure title, etc.) of the measure through notice-and-comment rulemaking. For example, if there is a substantive change to a measure in the measure specifications that changes the premise/overarching objective (that is, a screening measure that is changed to include treatment and follow-up) and/or clinical action of the measure, such substantive change would be proposed and identified through notice-and-comment rulemaking. We do not believe that it is necessary to propose or identify through notice-and-comment rulemaking changes to a measure that do not meet any of the above substantive change criteria for measures (for example, a modification to the title or domain that do not change or impact any element of the measure). We generally consider such changes to be non-substantive and would be published in subregulatory guidance (that is, release notes applicable to a measure). We believe that it is important to provide a clear delineation of substantive changes to be included in a rulemaking process versus our previous approach, which generally included any changes made to measure specifications, measure titles, and domain modifications (81 FR 77137). We found that many changes made to measures based on our previous approach were not substantive in nature and should not be classified as substantive changes. Thus, we believe that establishing the substantive change criteria for measures provides further clarity as to what we consider a substantive change, particularly as it relates to how a change affects and/or impacts a measure. We note that measures identified as having a substantive change would generally have an update to their applicable benchmark. For measures that meet the data completeness criteria, but do not a benchmark or meet case minimum (class 2 measures), they would be scored in accordance to our proposed scoring policy as outlined in section IV.A.3.e.(1)(c)(iii)(B) of this proposed rule.

In addition, we intend to align the utilization of terminology across CMS programs when appropriate and applicable for consistency purposes. Since the implementation of MIPS, we have referenced the term patient reported outcome as a type of measure, which is similar, but not exact to a measure type categorization reference in the CMS Blueprint. In order to align the categorization reference of such measure type under MIPS with the CMS Blueprint terminology, we are modifying how the term is referenced as a measure type under MIPS and will reference such measure type as patient-reported outcome-based performance measure (PRO–PM) starting with the 2022 MIPS performance period. We believe that such modification does not have any substantive implications, but is merely a minor technical change of semantics that enables the utilization of consistent terminology across CMS programs when referencing such measure type.

We seek public comment on our proposal to establish measure substantive change criteria that would be utilized by CMS to identify such measures.

(f) Request for Information Regarding the COVID–19 Vaccination by Clinicians Measure

As of July 7, 2021, the Centers for Disease Control and Prevention (CDC) reported that there are 33,582,352 cases of coronavirus disease 2019 (COVID–19) and 603,656 deaths [204] caused by COVID–19 at the time of publication of this proposed rule and subject to change. In 2020, COVID–19 was the third leading cause of death in the United States, exceeded only by cancer and heart disease.[205] Widespread vaccination to prevent COVID–19 will be critically important to stemming the morbidity and mortality caused by this disease. Three vaccines have received the FDA emergency use authorization (EUA) for the prevention of COVID–19 (Pfizer-BioNTech, Moderna, and Janssen) as of July 7, 2021. The EUA allows the Pfizer-BioNTech, Moderna, and Janssen COVID–19 vaccines to be distributed in the United States.[206] As of July 7, 2021, 331,651,464 vaccine doses have been administered.[207]

To address this urgent public health emergency, CMS began the development of the COVID–19 Vaccination by Clinicians measure for MIPS, which would assess the percentage of patients aged 18 years and older seen for a visit during the measurement period who have ever completed or reported having ever completed a COVID–19 vaccination series. The measure would be reported by MIPS eligible clinicians as a MIPS CQM to determine the percentage of patients seen for a visit during the measurement period who have ever completed or reported having ever completed a COVID–19 vaccination series, either from the submitting MIPS eligible clinician or another MIPS eligible clinician. The measure as specified (see Table Group AA of Appendix 1 of this proposed rule) allows clinicians to determine a patient's vaccination status and deliver a vaccine dose, if possible and appropriate. The measure is intended to capture whether or not clinicians take an appropriate step to ensure that their patients are vaccinated. Patients receiving hospice care at any time during the measurement period would be excluded from the patient population of measure. The measure allows for an exception if the COVID–19 vaccination series was not administered, as documented by a MIPS eligible clinician, due to patient contraindication, or vaccine availability.

Between November of 2020 and January of 2021, we solicited feedback on the measure from measure-specific multi-stakeholder expert workgroups, specifically the Measure Application Partnership (MAP) coordinated through the National Quality Forum.[208] While the MAP agreed that the COVID–19 Vaccination by Clinicians measure could be an important tool to: Support vaccine uptake by collecting valuable information from the field, provide feedback to clinicians, and help identify where to conduct targeted education and outreach to limit the spread of infections, the MAP expressed concerns regarding the following elements of the measure: The patient population that would be assessed to measure performance (the inclusion of assessing patients who received 1 dose of a COVID–19 vaccine versus only assessing patients who received a complete COVID–19 vaccination series), and lack of available evidence and clinical guidance for vaccine

[204] *https://covid.cdc.gov/covid-data-tracker/#cases_totalcases.*

[205] *https://www.scientificamerican.com/article/covid-19-is-now-the-third-leading-cause-of-death-in-the-u-s1/.*

[206] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.*

[207] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html.*

[208] *http://www.qualityforum.org/map/.*

administration (the feasibility of implementing the measure given the limited vaccine supply and availability, and the potential inconsistencies and discrepancies derived from the novelty of data collection and reporting for COVID vaccinations). We seek to mitigate such issues by obtaining further information and feedback from additional stakeholders. We intend to utilize the obtained information and feedback to inform measure specification improvements that would be implemented for a future performance period.

We seek public comment on the draft COVID–19 Vaccination by Clinicians measure specifications, which is available on the Quality Payment Program website in the Resource Library located at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1471/Draft%20COVID-19%20Vaccine%20Specs.pdf*. Specifically, we are seeking feedback on the following questions. Should the measure assess whether or not patients completed a COVID–19 vaccination series to capture provision of effective clinical care and why? Given that there are differences in the age ranges for patients eligible to receive the various COVID–19 vaccinations (Moderna and Janssen COVID–19 vaccines are authorized for patients ages 18 years and older; Pfizer-BioNTech COVID–19 vaccine is authorized for patients ages 12 and older; and future COVID–19 vaccines may be approved for other age ranges that are implemented after the publication of this proposed rule), is 18 years and older an appropriate initial age threshold for this measure? Given the current COVID–19 PHE and the intent of the measure, should this measure be mandatory for reporting in a future year? If this measure would be mandated as a required measure for reporting purposes under MIPS, what issues or concerns would need to be considered and/or mitigated regarding the implementation of the measure in a future year? What are the potential unintended consequences associated with the potential future implementation of the measure as specified in Table Group AA of Appendix 1 of this proposed rule and applicable measure specifications? What are the feasibility challenges and barriers to implementing the measure? What are the potential options and/or recommendations that we should consider to address and/or mitigate the feasibility challenges and barriers to be experienced during the 2022 MIPS performance period that could be improved upon for the 2023 MIPS performance period? If this measure would be mandated, how would the collection of the measure data be useful after the 2023 MIPS performance period?

(g) Quality Data Submission Criteria

(i) CAHPS for MIPS Background

As part of the CY 2021 PFS final rule (85 FR 84718), we finalized the policy requiring Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) to report quality data via the Alternative Payment Model (APM) Performance Pathway (APP). Beginning with the 2021 MIPS performance period, Shared Savings Program ACOs are required to field the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS survey as part of the APP. We previously established in the CY 2019 PFS final rule that MIPS quality benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APM Entities, to the extent feasible, during the applicable baseline or performance period (83 FR 59842). Given that Shared Savings Program ACOs will now be required to field the CAHPS for MIPS survey as part of the APP, we note that beginning with the 2022 MIPS performance period CAHPS for MIPS survey, the CAHPS for MIPS benchmarks will be calculated based on summary survey measure (SSM) scores from MIPS groups and APM entities (including Shared Savings Program ACOs) that fielded the CAHPS for MIPS Survey in the applicable baseline or performance period. Furthermore, the CAHPS for MIPS SSM scores will be adjusted for patient case-mix using a single case-mix adjustment model that incorporates data from both MIPS groups and APM entities (including Shared Savings Program ACOs) that field the CAHPS for MIPS Survey.

Beginning with the 2022 MIPS performance period/2024 MIPS payment year for the CAHPS for MIPS survey, to further support the alignment of CAHPS for MIPS sampling and scoring procedures between Shared Savings Program ACOs and MIPS groups, we are proposing to adopt certain policies that had been part of the CAHPS for ACOs survey administration process, but have not previously been a part of CAHPS for MIPS. These policies fall into 3 broad categories: Sampling, case mix adjustment, and scoring; for policies related to certified survey vendors rendering the CAHPS for MIPS survey for subgroups, please see section IV.A.3.h. of this rule. We are requesting comment on the following proposals related to CAHPS for MIPS.

(ii) CAHPS for MIPS Sampling Specifications

The CAHPS for MIPS Survey is administered to a sample of eligible patients for all Shared Savings Program ACOs and for those MIPS groups that elect the measure. Prior to drawing the sample, patients are excluded from the pool of potential survey recipients (called the sampling frame) for a number of reasons, including if they are known to have died or are known to be institutionalized. Currently, patients are considered institutionalized if 100 percent of their primary care charges are associated with an institutionalized setting during the sampling period. Starting in the 2018 performance period, the CAHPS for ACOs survey additionally flagged patients as institutionalized if their *last* primary care visit during the sampling period was associated with an institutional setting. This change (called the ''last primary care visit rule'') was made to better identify and exclude from the sample, patients likely to be institutionalized at the time the survey is fielded, and by extension, to improve response rates on the survey. This was of particular importance for a few Shared Savings Program ACOs for which large portions of their assigned beneficiaries are in nursing homes. Analysis of the 2020 performance period CAHPS for MIPS sample found that among the 100 MIPS groups that fielded the survey, less than 1 percent of the survey sample would be lost, on average, due to the application of this additional criterion to identify institutionalized patients. Of the groups fielding the survey in 2020 performance period, only 1 would have been excluded from participating in the survey as a result of falling below the minimum sampling threshold due to the expanded definition of institutionalization. Given these findings, which suggest a minimal impact on MIPS group sample sizes and eligibility to field the survey, we propose beginning with the 2022 MIPS performance period for the CAHPS for MIPS survey to add the ''last primary care visit rule'' as an additional exclusion to sampling for the CAHPS for MIPS survey. We expect that this change will better identify and exclude from the sample those patients likely to be institutionalized at the time the survey is fielded, and by extension, will improve response rates on the survey.

Other CMS programs use different CAHPS surveys to gather information on patient experience in a variety of health

care settings. The In-Center Hemodialysis (ICH) CAHPS survey is fielded twice per year to patients receiving dialysis treatment at an ICH facility. Previously, patients sampled for the ICH CAHPS survey during the spring implementation were removed from the CAHPS for ACOs sampling frame in an effort to improve response rates to the ICH CAHPS Survey and to avoid burdening patients with multiple surveys. Analyses of the 2019 and 2020 performance periods CAHPS for MIPS sampling frames suggest that implementing ICH CAHPS deduplication in CAHPS for MIPS would have only minor impacts on most MIPS groups. Of the groups fielding the survey in the 2020 performance period, only 1 would have been excluded from participating in the survey due to falling below the minimum sampling threshold following ICH CAHPS deduplication (the same group that would have been excluded due to the ''last primary care visit rule'', above). For the 2019 performance period, no participating groups would have been excluded. Therefore, we propose beginning with the 2022 MIPS performance period for the CAHPS for MIPS survey to remove patients who were sampled for the Spring ICH CAHPS survey from the sampling frames for CAHPS for MIPS. We expect this change would have only a minor impact on the CAHPS for MIPS sampling frame, but would increase response rates to the ICH CAHPS Survey and avoid burdening patients with multiple surveys.

(iii) CAHPS for MIPS Case-Mix Adjustment Model

Under CAHPS for MIPS, we adjust summary survey measure scores for case-mix to promote meaningful comparison of the performance of MIPS groups despite differences in their patient populations (81 FR 77120). The case-mix adjustment model for CAHPS for MIPS includes the following case-mix adjustors: Age; education; self-reported general health status; self-reported mental health status; proxy response; Medicaid dual eligibility; and eligibility for Medicare's low-income subsidy. The CAHPS for ACOs Survey included an additional adjustor, Asian language survey, following prior literature that recommended adjustment for Asian language surveys to account for cultural differences that affect reporting. The CAHPS for MIPS case-mix adjustment model has historically not included this adjustor because no Asian language surveys have been administered. Because Shared Savings Program ACOs are fielding the CAHPS for MIPS survey as of the 2021 MIPS performance period, we propose beginning with the 2022 MIPS performance period CAHPS for MIPS survey to add use of an Asian language survey as a case-mix adjustor to the CAHPS for MIPS case-mix adjustment model. Use of an Asian language survey has been shown to be significantly associated with specific response patterns to a number of survey items that contribute to summary survey measures. In particular, Asian language survey respondents are generally less likely to use responses at the extremes of the scales, which tends to result in lower overall scores compared to patients who respond to English-language surveys. Therefore, it is important to retain use of Asian language survey as a case-mix adjustor for Shared Savings Program ACOs, and also appropriate to include it in the case-mix adjustment model for MIPS groups should Asian language surveys be completed for these groups in the future. Analysis of 2019 performance period CAHPS for MIPS data found that adding the Asian language survey case-mix adjustor and pooling data from MIPS groups and Shared Savings Program ACOs for the purposes of case-mix adjustment had only a minimal impact on mean scores for MIPS groups, with scores increasing slightly as a result.

(iv) Scoring CAHPS for MIPS Summary Survey Measures

The CAHPS for MIPS survey contains 10 summary survey measures (SSMs). Of these, 8 are benchmarked and scored, while the other 2 (*Health Status and Functional Status and Access to Specialists*) are unscored and included for informational purposes only. The latter 2 measures had previously been scored, but were changed to unscored starting with the 2018 performance period (82 FR 53720). While *Health Status and Functional Status* was changed to unscored because it assesses underlying characteristics of a group's patient population and is less of a reflection of patient experience of care with the group, the Access to Specialists SSM was changed to unscored due to historically low reliability and response rates. At the same time this change was made (2018 performance period), a shorter, streamlined version of the CAHPS for MIPS Survey was implemented (82 FR 53632). Since the implementation of the shortened survey, which included a reduction in the number of survey items that make up the *Access to Specialists* SSM, response rates and reliability for this SSM have improved dramatically, with over 80 percent of MIPS groups achieving acceptable reliability on this SSM in 2018, 2019, and 2020 performance period(s), compared to less than 20 percent in 2017 performance period. Therefore, because CMS no longer has analytic concerns about scoring the measure, we propose beginning with the 2022 MIPS performance period for the CAHPS for MIPS survey to once again benchmark and score the *Access to Specialists* measure, which would mean there would be 9 SSMs included in the CAHPS for MIPS scoring process, with 1 SSM remaining unscored.

We request comments on these proposed changes to the CAHPS for MIPS policies and scoring process.

(2) Cost Performance Category

(a) Background

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, and CY 2021 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through 59776, 84 FR 62959 through 62979, and 85 FR 84877 through 84881, respectively) for a description of the statutory basis and existing policies pertaining to the cost performance category.

In this proposed rule, we are proposing to add 5 new episode-based measures to the cost performance category beginning with the 2022 performance period, and to update the operational list of care episode and patient condition groups and codes. Additionally, we are proposing a new process for stakeholders to develop cost measures for MIPS. Finally, we are proposing to establish criteria for determining whether a cost measure change is considered substantive starting with the 2022 MIPS performance period. These proposals are discussed in more detail in the following sections.

(b) Addition of Episode-Based Measures

(i) Background

Under § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. We will continue to evaluate cost measures that are included in MIPS on an ongoing basis and anticipate that measures could be added, modified, or removed through rulemaking as measure development continues. Any substantive changes to a measure would be proposed for adoption in future years through notice and comment rulemaking, following review by the Measure Applications Partnership (MAP). The MAP is a multi-stakeholder partnership that provides guidance to

CMS on performance measures for use in federal health programs—more information is available at *https://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx*. The MAP provides an additional opportunity for an interdisciplinary group of stakeholders to provide feedback on whether they believe the measures under consideration are applicable to clinicians and complement program-specific statutory and regulatory requirements. Through its Measure Selection Criteria, the MAP focuses on selecting high-quality measures that address the National Quality Strategy (NQS)'s three aims of better care, healthy people/communities, and affordable care, as well as fill critical measure gaps and increase alignment among programs.

We would take all comments and feedback from both the public comment period and the MAP review process into consideration as part of the ongoing measure evaluation process. Some modifications to measures used in the cost performance category might incorporate changes that would not substantively change the measure. Examples of such non-substantive changes may include updated telehealth service codes, diagnosis or procedure codes or risk adjustors. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. However, as described in section 7 of the Blueprint for the CMS Measures Management System Version 16.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*), if substantive changes to these measures become necessary, we expect to follow the pre-rulemaking process for new measures, including resubmission to the Measures Under Consideration (MUC) list and consideration by the MAP.

In section IV.A.3.d.(2)(b)(ii) of this proposed rule, we have summarized the timeline for measure development, including stakeholder engagement activities undertaken by the measure development contractor, an entity that oversees the development, implementation and maintenance of cost measures in accordance with a contract with CMS. In sections IV.A.3.d.(2)(b)(iii) through IV.A.3.d.(2)(b)(vii) of this proposed rule, we summarize the new measures that would be included in the cost performance category for the CY 2022 performance period and future performance periods. For the new chronic condition episode-based measures, we provide detail about the measure framework, which lets attributed clinicians or clinician groups know the cost of care that is clinically related to their management of a patient's chronic condition during an episode of care (''episode'').

(ii) Overview of Measure Development Timeline for New Episode-Based Measures

We develop episode-based measures to represent the cost to Medicare and beneficiaries for the items and services furnished during an episode. Episode-based measures are developed to compare clinicians on the basis of the cost of care that is clinically related to their treatment and management of a patient and provided during the episode's timeframe. Specifically, we define cost based on the allowed amounts on Medicare claims, which include both Medicare trust fund payments and any applicable beneficiary deductible and coinsurance amounts.

The measure development contractor has continued to seek extensive stakeholder feedback during measure development, building on the processes outlined in the CY 2018 QPP final rule (82 FR 53644 through 53645) and discussed in detail in the CY 2019 PFS final rule (83 FR 59767 through 59769). These processes include the measure development contractor convening multiple panels for different purposes, conducting national field testing of the developed measures, and seeking input from clinicians and stakeholders through engagement activities. The technical expert panel (TEP) serves a high-level advisory role and provides guidance to the measure development contractor on the overall direction of development; clinical subcommittees provide the measure development contractor with recommendations on the measures to prioritize for development within specific clinical areas and on the scope for the measures; and measure-specific clinician expert workgroups provide the measure development contractor recommendations on clinical specifications for each measure. More information about the measure development process for the 5 measures we are proposing to include is available in the measure development process document located on the MACRA Feedback Page at *https://www.cms.gov/files/document/macra-cmft-ebcm-process-2020.pdf*. Summaries of the clinical subcommittee and clinician expert workgroup meetings organized by measure development contractor are also available on the MACRA Feedback Page under the ''Wave 3 MACRA cost measure development (2019–2020)'' section located at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*.

We provided stakeholders an opportunity to review their performance under the new episode-based measures through national field testing, from August 17, 2020, to September 18, 2020. Clinicians and clinician groups meeting a minimum threshold of episodes for each measure could review their field test report and an episode-level file with detailed information to understand the types of services that comprise a large or small share of their episode costs. In response to stakeholder input from previous field-testing periods, the field test reports were changed to a portable document format (PDF) and distributed through the Quality Payment Program portal, which clinicians routinely access to review their MIPS performance feedback reports. In addition, stakeholders could review a number of supporting documents, including draft measure specifications, an overview of the development process, a fact sheet and frequently asked questions (FAQ) document and summary statistics on each of the measures. These documents were available through the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*). A summary of stakeholder feedback from the field testing period is also available on the website (*https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*).

During field-testing, the measure development contractor also collected person and family engagement (PFE) input from patients with lived experience of the condition in question. The measure development contractor summarized input about their experience of care, including clinicians who were part of their care team, the types of services they received, and areas they identified for improvement in their care. For more information, we refer readers to the *Summary of Person and Family Engagement (PFE) and Input for Wave 3 Episode-Based Cost Measure Development,* which summarizes PFE input that the measure development contractor gathered for the measures (*https://www.cms.gov/files/document/summary-person-and-family-engagement.pdf*).

Similar to previous years, the measure development contractor has continued

to engage clinicians and stakeholders, conducting extensive outreach activities. These activities included general informational email blasts, targeted email outreach to specialty societies, hosting office hours to gather information on additional opportunities for participation and outreach, and posting a pre-recorded MACRA Cost Measures Field Testing Webinar to provide information about the measure development process and field test reports (available at *https://qpp.cms.gov/resources/webinars*).

(iii) New Episode-Based Measures for CY 2022 and Future Performance Periods

In this section of the proposed rule, we discuss the 5 new episode-based measures, including 2 new chronic condition measures, which we propose to add for the CY2022 and future performance periods. These measures are listed in Table 41. The acute inpatient medical condition and procedural measures are based on the previously established framework for episode-based measures, which we described in detail in the CY 2019 PFS final rule (83 FR 59767 through 59773).

Chronic condition episode-based measures expand on the previously established framework for episode-based measures to address unique factors inherent to the continuous nature of chronic disease care management. In section IV.A.3.d.(2)(b)(vi) of this proposed rule, we provide detail about the proposed episode definition and attribution methodology for chronic condition episode-based measures. After chronic condition episodes are defined and attributed to a clinician group and, or individual clinician, we include items and services furnished during the episode that are clinically related to the care and management of a patient's chronic condition. Items and services may include treatment and diagnostic services, ancillary items (such as medical nutrition therapy and refining and maintenance of a portable pump for diabetes), services directly related to treatment, and those furnished as a consequence of care. The two chronic condition measures specified in this proposed rule are calculated using claims data from Medicare Parts A, B, and D. Part D costs are included to account for the full range of treatment options used to manage chronic conditions. As with Part A and B payment standardization, Part D costs are standardized to facilitate meaningful comparisons of resource use within the market-based Medicare Part D program by accounting for non-clinical variation in costs. For more detail, the Part D payment standardization methodology is available at *https://resdac.org/articles/cms-price-payment-standardization-overview*. The Medicare Parts A and B payment standardization methodology is available at *https://resdac.org/articles/cms-price-payment-standardization-overview*.

Similar to other episode-based measures, chronic condition measures include features intended to ensure a more accurate comparison of costs across clinicians. First, we stratify the patient population captured by the measure into smaller, clinically similar patient cohorts. For example, the Diabetes measure separates patients with type 1 and type 2 diabetes, and the risk adjustment model is assessed at the level of each stratification to ensure that only patients with similar case mixes are compared to each other. We note that the term ''stratification'' will be used to describe a portion of a group in relation to the cost performance category and that such term is synonymous with the term ''episode sub-group'' used in the cost measure specification documents and other documents related to the cost performance category. In general, unless otherwise indicated, the term ''episode sub-group'' used in the cost measure specification documents and other documents related to the cost performance category has a different meaning than the term ''subgroup'' that we propose to define under § 414.1305 in this proposed rule. Second, we standardize episode costs to limit observed differences in costs to those that may result from health care delivery choices. Third, we exclude unique groups of patients from episodes where it may be unreasonable to compare the costs of these patients to the whole cohort. Last, the measures account for patient characteristics that can influence spending and are outside of a clinician's control using risk adjustment. For example, the risk adjustment model is run separately for patients with and without enrollment in a Part D drug plan to account for differences in costs that we might observe between patients enrolled in Part D and those who are not. In addition, the risk adjustment model for chronic condition episode-based measures specified in this rule account for a patient's status as a dual Medicare and Medicaid enrollee. This was based on testing demonstrating that dual status had a notable impact on performance for the two measures. For more information on the chronic condition episode-based measure framework, we refer readers to the Chronic Condition Cost Measure Framework located at *https://www.cms.gov/files/document/chronic-condition-cost-measure-framework-poster.pdf*.

The proposed specifications for all 5 proposed episode-based measures are available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* The specifications documents for each measure consist of a methods document that describes the steps for constructing the measure and a measure codes list file that contains the medical codes used in that methodology. First, the methods document provides details about components of episode-based measures: Identifying patients receiving care, defining an episode-based measure, attributing episodes to clinicians and clinician groups, assigning costs, defining exclusions, risk adjusting, and calculating measure score. For each measure component, the methods document provides detailed methodology describing each logic step involved in constructing the measure. For the chronic condition episode-based measures, the specifications also include an appendix to the methods document which provides additional detail on particular components of the measure construction framework, including the sub-grouping methodology, episode construction and calculation, and attribution to individual clinicians. Second, the measure codes list contains the codes used in the measure specifications, including the episode triggers, attribution, sub-groups, assigned items and services, exclusions, and risk adjustors.

More information about the five proposed episode-based measures is available in the measure justification forms, the national summary data report, and the national summary data report addendum with risk adjustment regression results. These documents are available through the MACRA Feedback Page (*https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*).

We seek public comment on the proposed episode-based measures, which are listed in Table 41.

TABLE 41: Proposed Episode-Based Measures Beginning With CY2022

Measure Name	Episode Type
Melanoma Resection	Procedural
Colon and Rectal Resection	Procedural
Sepsis	Acute inpatient medical condition
Asthma/Chronic Obstructive Pulmonary Disease (COPD)	Chronic condition
Diabetes	Chronic condition

(iv) Attribution

In this section of the proposed rule, we discuss the attribution methodology for the episode-based measures. In the CY 2020 PFS final rule (84 FR 62962), we established at § 414.1350(b)(8) that beginning with the 2020 performance period, each cost measure is attributed according to the measure specifications for the applicable performance period. For the proposed acute inpatient medical condition and procedural episode-based measures, we refer readers to the proposed measure specifications for the attribution methodology, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.* For the proposed chronic condition measures, we would use a new attribution framework for identifying and confirming a clinician-patient relationship, which we discuss below. For further detail regarding the specific attribution methodology for the proposed Asthma/COPD and Diabetes measures, we refer readers to the measure specifications for each measure, available at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.*

For chronic condition episode-based measures, we would attribute episodes to the clinician group that renders the services that constitute a trigger event, which is identified by the occurrence of two claims billed in close proximity by the same clinician group. Both claims must have a diagnosis code indicating the chronic disease captured by the measure (for example, type 1 or type 2 diabetes for the Diabetes episode-based measure). The first claim must have an evaluation and management (E/M) code for primary care services and the second claim must have either another E/M code for primary care services or a condition-related HCPCS/CPT code for procedure codes related to the treatment or management of the chronic condition. The trigger event opens a year-long attribution window from the date of the initial E/M primary care service, during which the same clinician group could reasonably be considered responsible for managing the patient's chronic disease. The initiation of the attribution window at the onset of the trigger event ensures that costs are attributed only after the start of the clinician-patient relationship. We may extend the initial attribution window and the clinician group's responsibility by another year each time we see additional E/M codes for primary care services or condition-related HCPCS/CPT codes for procedure codes related to the treatment or management of the chronic condition that indicate an ongoing clinician-patient relationship. Therefore, the resulting total attribution window can span multiple years and vary in length for different patients. Because the total attribution window can span multiple performance periods, we measure it incrementally and periodically by dividing it into segments of episodes, which we assess in the performance period in which they conclude. Dividing the total attribution window into episodes allows us to assign costs during the time-period in which the clinician group is responsible for the patient's chronic condition care management.

After we identify the attributed clinician group as described in the previous paragraph, we would attribute the episode to individual clinician(s). For individual clinicians, we would attribute episodes to each MIPS eligible clinician within an attributed clinician group that renders at least 30 percent of qualifying services during the episode. Qualifying services include E/M codes for primary care services or condition-related HCPCS/CPT codes with a relevant chronic condition diagnosis. We employ two additional checks to confirm the qualifying clinician's role in the ongoing management of the patient's chronic condition. First, we check to ensure that the qualifying clinician(s) have rendered at least one E/M code for primary care services or condition-related HCPCS/CPT code with a relevant diagnosis within 1 year prior to or on the episode start date. This ensures that clinicians are not attributed an episode before they have their first encounter with the patient. Second, we check whether the clinician(s) have written at least 2 condition-related prescriptions on different days to two different patients during the performance period plus a one-year lookback period. The use of these prescription billing patterns ensures that we are capturing the clinicians actually involved in providing ongoing chronic care management, rather than clinicians who may have only refilled a patient's prescription once, as a courtesy. MIPS eligible clinicians within an attributed clinician group that render at least 30 percent of qualifying services and meet the two additional checks are considered for attribution. The individual clinician's performance is based on all of the episodes attributed to the individual clinician, whereas the clinician group's performance is based on all of the episodes attributed to the clinician group. If a single episode is attributed to multiple clinicians in a single clinician group, the episode is only counted once toward the clinician group's performance. Additional detail for this attribution methodology is available in the proposed measures specifications for the Diabetes and Asthma/COPD measures located on the MACRA Feedback Page at *https://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.*

To illustrate the proposed attribution rules for chronic condition episode-based measures, we are providing an example of a clinical scenario where 3 MIPS eligible clinicians (A, B, and C) are part of the same clinician group. A patient with type 2 diabetes presents to the clinician group to receive services related to their condition. Clinician A bills an initial E/M code for primary care services related to the patient's diabetes (for example, an office/outpatient visit related to the patient's diabetes). During a follow-up appointment two weeks later, Clinician A bills a HCPCS/CPT code for tests related to the patient's diabetes. We consider the occurrence of these two services to constitute a trigger event

indicating the start of a clinician-patient relationship. This trigger event opens a one-year attribution window from the date of the initial E/M service and the clinician group that rendered the trigger event services would be attributed the Diabetes episode. If in this example, there were a total of 10 clinically related services captured during the episode, and Clinician A rendered 5 of those services, Clinician B rendered 2, and Clinician C rendered 3 of those services, then Clinicians A and C would be considered for attribution since they would have rendered at least 30 percent of qualifying services for the patient. Clinician B would not be considered for attribution. Before attributing the episode to Clinicians A and C, we check (i) whether the clinicians billed at least 1 E/M code for primary care services or condition-related HCPCS/CPT code with a relevant diabetes diagnosis within 1 year prior to or on the episode start date and (ii) whether they wrote 2 diabetes-related prescriptions on different days for 2 different patients during the performance period plus a one-year lookback period. Assuming Clinician A met these two checks and Clinician C did not, then only Clinician A would be attributed this Diabetes episode. This episode would count towards the Diabetes measure's case minimum for Clinician A, but not for Clinicians B or C. At the group reporting level, the episode would be included in the calculation of the clinician group's measure score and would count towards the measure's case minimum for the clinician group.

(v) Discussion of MAP Recommendations for New Episode-Based Measures

In this section of the rule, we discuss the results of the 2020–2021 MAP review cycle for the 5 measures we are proposing and address the points raised by the MAP. Following the measure development process, we describe in section IV.A.3.d.(2)(b)(ii) of this proposed rule, the MAP Clinician Workgroup and the MAP Coordinating Committee reviewed the 5 measures in January 2021. The MAP conditionally supported Melanoma Resection and Colon and Rectal Resection contingent on NQF endorsement. We intend to submit these 2 measures to a future NQF endorsement cycle, as we have done for other episode-based measures. The MAP recommended ''do not support with potential for mitigation'' for the Sepsis, Diabetes, and Asthma/COPD measures; we address these mitigation points in turn, below in this section.

The mitigation factors across the 3 measures focused primarily on testing. Across the 3 measures, the MAP noted the following mitigation points: (1) Explore the correlations between the cost measure and quality measures; and (2) NQF endorsement. For the Asthma/COPD and Diabetes measures, the MAP noted the following points: (1) Explore the concern that good care may result in higher episode costs but with global cost savings; and (2) evaluate the connection between upstream interventions and downstream cost savings. For the Sepsis measure, the MAP's recommendation was contingent on an analysis into the potential for gaming associated with the over-diagnosis of sepsis. For all 3 measures, the MAP noted that should testing data show that the measure appropriately assesses episode-based cost and can be used alongside quality measures, the measures would be valuable to add to the program. The MAP's final recommendations are available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

We appreciate the MAP's review and their comments regarding the measures. We believe that we have addressed the mitigating factors by sharing additional testing information and clarifying the measure construction and intent at the MAP Coordinating Committee meeting on January 25, 2021.

The first mitigation factor common to the Asthma/COPD, Diabetes, and Sepsis episode-based measures is to explore the correlations with quality measures to address concerns about the potential for care stinting. We presented empirical testing results to the MAP Coordinating Committee on January 25, 2021. The MAP's concern about care stinting would be evidenced by a strong, inverse cost-quality correlation between cost and quality measures; that result would indicate that good performance on cost would be associated with poor performance on quality and that variation in cost is solely reflecting variation in quality. We do not see this relationship in any of the correlations. The correlation results instead indicate a modest and generally positive correlation between the 3 cost measures and related quality measures demonstrating that there is variation in cost, regardless of quality level. These results suggest that performance on these 3 episode-based measures can be improved without negatively impacting quality. More information on the results of this exploration of the relationship between cost and quality measures is available in the supplemental testing document at *https://www.cms.gov/files/document/testing-updates-wave-3.pdf.*

The second mitigation factor common to the Asthma/COPD, Diabetes, and Sepsis episode-based measures is NQF endorsement. We intend to submit these measures to a future NQF endorsement cycle, as we have done with other cost measures. For example, the MAP in the 2018–2019 review cycle had recommended ''do not support with potential for mitigation'' for the total per capita cost measure. This measure was endorsed by NQF in December 2020.

For the Asthma/COPD and Diabetes measures, the MAP raised two points for further evaluation. The first point is to evaluate the relationship between condition-specific costs and global patient costs, as the MAP was concerned that there may be tension between these types of costs. We tested the correlation between the episode-based measures and NQF #3575 total per capita cost, a population-based cost measure that assesses the overall costs of care. The correlation results show a moderately positive correlation between Asthma/COPD and Diabetes and the total per capita cost measure, indicating that clinicians who have lower costs for the specific care of asthma/COPD and diabetes tend to also have lower overall global costs. These results suggest that there is no concern that high quality care results in higher episode-specific costs and lower overall costs. These results also show that there is no redundancy between the measures; for instance, a correlation of 1 would indicate duplication across the episode-based and population-based cost measures. The results of this correlation testing are available at *https://www.cms.gov/files/document/testing-updates-wave-3.pdf.*

For the Asthma/COPD and Diabetes measures, the MAP's second point was to evaluate the potential for actionability, providing the example of the connection between upstream medical interventions and downstream costs. The MAP's recommendations note that this example was clarified as cost measures do not attempt to dictate clinician practice; that would be outside of their scope. Rather, the cost measures aim to fairly capture costs related to a clinician's care and account for factors outside of their influence. Regarding the overall actionability, we selected these measures to develop based on the evidence from the literature and input from clinical experts which identified the care and management of asthma, COPD, and diabetes as important in the goal of making care affordable, due to their prevalence and costliness, and the nature of the care as clinicians can make

care decisions that reduce the likelihood of high costs. For example, opportunities for clinicians to take action in the Asthma/COPD episode-based measure identified through an environmental scan, clinician input, and input from persons with lived experience of the conditions include enhancing education programs, support, and care continuity; providing appropriate medication and encouraging adherence to these medications; promoting pulmonary rehabilitation through physical activity and exercise; and encouraging smoking cessation. For the Diabetes episode-based measure, actions to decrease the likelihood of high costs include providing self-management education and support, providing appropriate medication, screening for other impairments, and encouraging adherence to preventive treatment guidelines.

The MAP noted a mitigation point for the Sepsis measure to explore a concern related to over-diagnosis of sepsis which could result in potential gaming of the measure. The variation in diagnosis coding has been considered extensively throughout development, including by the Sepsis clinician expert workgroup convened by the measure development contractor. The specifications reflect these careful considerations by defining a homogenous patient cohort while retaining the breadth of coverage needed to address coding issues. The measure uses a risk adjustment approach and exclusions to ensure fair comparisons, for example by adjusting for source of infection and source of admission (to account for patients transferred from another facility), and stratifying the patient population based on severity (with and without septic shock). As such, the measure construction itself is designed to capture costs accurately to compare clinician cost performance. We also tested the relationship between cost measure performance and types of variation in coding, such as the attributed clinician's share of episodes triggered by MS–DRGs 870–872 for sepsis and share of episodes out of all hospitalizations with 24 MS–DRGs for other infectious disease. The results of these correlations show no meaningful relationship between cost measure scores and coding patterns, addressing the concern about the impact of diagnosis coding on measure scores.

We appreciate the MAP's comment that the Asthma/COPD, Diabetes, and Sepsis measures would be valuable to add to MIPS, should testing data show that the measures appropriate assess costs. We believe that the extensive empirical testing throughout and after development (beyond the testing referenced in this section), national field testing, and engagement with clinician experts and incorporation of the patient voice demonstrate that the measures appropriately capture costs related to the care of these conditions. For more testing information, see *https://www.cms.gov/files/document/testing-updates-wave-3.pdf.*

(vi) Proposed Revisions to the Operational List of Care Episode and Patient Condition Groups and Codes

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve the physician, practitioner, and other stakeholder communities in enhancing the infrastructure for cost measurement, including for purposes of MIPS and APMs. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from stakeholders, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other stakeholders.

In December 2016, we published the Episode-Based Measure Development for the Quality Payment Program (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-list-of-episode-groups-and-trigger-codes-December-2016.zip*) and requested input on a draft list of care episode and patient condition groups and codes as required by sections 1848(r)(2)(E) and (F) of the Act. In accordance with section 1848(r)(2)(G) of the Act, in January 2018, we posted an operational list of 8 care episode groups and patient condition groups, which is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-Operational-List-of-Care-Episode-and-Patient-Condition-Codes.zip.* Under section 1848(r)(5)(A)(iii) of the Act, to evaluate the resources used to treat patients with respect to care episode and patient condition groups, the Secretary shall, as the Secretary determines appropriate, conduct an analysis of resource use with respect to care episode and patient condition groups. In accordance with this section, we used the 8 care episode groups and patient condition groups included in the operational list as the basis for the 8 episode-based measures that were finalized for use in MIPS in the CY 2019 PFS final rule (83 FR 59767 through 59773). In the CY 2020 PFS final rule (84 FR 62968 through 62969), in accordance with section 1848(r)(2)(H) of the Act, we revised the operational list beginning with CY 2020 to include 10 additional care episode and patient condition groups, which served as the basis for the 10 additional episode-based measures that were refined based on extensive stakeholder input and finalized for use in MIPS in that same final rule (84 FR 62979). The operational list as revised in the CY 2020 PFS final rule is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.*

Under section 1848(r)(2)(H) of the Act, we are proposing to revise the operational list beginning with CY 2022 to include 5 new care episode and patient condition groups, based on input from clinician specialty societies and other stakeholders. These 5 care episode and patient condition groups were included in the draft list that we posted in December 2016 and refined based on extensive stakeholder input as described in section IV.A.3.d.(2)(b)(ii) of this rule. The codes and logic used to define these episode groups are available on our MACRA Feedback Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html.* These care episode and patient condition groups serve as the basis for the 5 new episode-based measures that we are proposing for the cost performance category in section IV.A.3.d.(2)(b)(iii) of this rule. We request comments on our proposal to revise the operational list to include these 5 new care episode and patient condition groups.

(vii) Reliability and Case Minimum

In this section of the rule, we discuss the case minima for the 5 proposed cost

measures, weighing up considerations of reliability standards, the tradeoffs between accuracy and reliability, and the implications of increasing case minima on the extent to which the measure can apply to clinicians participating in MIPS. Reliability is a metric that evaluates the extent that variation in a measure comes from clinician performance (''signal'') rather than random variation (''noise''). Higher reliability suggests that a measure is effectively capturing differences between the clinician and their peer cohort.

In the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77171), we identified reliability levels between 0.4 to 0.7 as moderate and reliability levels above 0.7 as high. In the CY 2017 Quality Payment Program final rule, we also identified a threshold of 0.4 for mean reliability to be applied for measures in the cost performance category to ensure moderate reliability. This aligned with the reliability threshold applied to measures under the Value Modifier program and previous analyses of reliability.[209] We appreciate the concerns commenters had raised that this may be too low and as we noted in the CY 2017 Quality Payment Program final rule (81 FR 77169 through 77171), we continue to work on developing measures with the highest level of reliability that is feasible within the MIPS program and have since continued to monitor the overall scientific evidence on reliability. There are many different interpretations of reliability and what these values represent. Studies have pointed to various standards to indicate sufficient, adequate, moderate, or good reliability across healthcare and other disciplines with performance measures and different methods of estimating reliability.[210] [211] [212] [213] [214] [215] [216] We also monitor the evaluation and standards applied throughout the measure endorsement processes, and note that the endorsement standards state there is no minimum threshold for reliability.[217] As such, we believe that the 0.4 threshold for mean reliability continues to be appropriate for moderate reliability.

Under section 1848(r)(5)(A) of the Act, to evaluate the resources used to treat patients (with respect to care episode and patient condition groups), the Secretary shall, as the Secretary determines appropriate, conduct an analysis of resource use (with respect to care episodes and patient condition groups of such patients) using codes reported on claims. Our approach to cost measurement focuses on defining clinically homogenous patient conditions and care episodes. This ensures that these measures accurately compare clinician performance without the results being solely driven by clinical differences across episodes. While limiting the measure scope to improve homogeneity improves the accuracy of assessing cost performance, this also reduces the number of episodes per clinician. Fewer episodes per clinician results in lower reliability compared with global population measures. However, episode-based measures balance this concern using selective service assignment; only including the costs of services that are clinically related to the condition or procedure in the measures' cost calculation improves reliability by keeping the ''signal'' while reducing the ''noise.'' [218] Overall, these measures prioritize capturing clinically appropriate, homogeneous care episodes over achieving results on certain testing mechanisms to meet the statutory objective of episode-based resource measurement and create more actionable measures for clinicians. As such, we continue to evaluate cost measures on a broader range of testing, along with the details of measure construction. For this reason, we continue to caution against placing too much emphasis on reliability results in isolation as we noted in the CY 2018 Quality Payment Program proposed rule (82 FR 30050 through 30051).

As we discussed in the CY 2018 Quality Payment Program proposed rule (82 FR 30050 through 30051), while a higher case minimum generally improves measure reliability, these incremental increases must be considered against decreases in the coverage of the measure. There are several important implications for clinicians and the program. Increasing the case minimum reduces the number of clinicians that can have their performance assessed by that measure. This can limit the applicability of episode-based measures to larger group practices with sufficient case volume, leaving smaller practices and individual practitioners to be assessed only with population-based cost measures. In addition, for measures to have the potential to improve performance, they should apply to as many clinicians as can be reliably measured. Finally, it is important to recall that clinicians receive a cost performance category score which incorporates their scores across all applicable cost measures. Adding more measures that can be used in a category score increases the amount of data used to calculate the category score, which may improve the precision of overall assessment of cost performance. Additional measures also allows us to evaluate clinicians' cost category performance across a broader range of their care practice.

We examined the reliability of the 5 proposed episode-based measures, and Table 42 presents the percentage of TINs and TIN/NPIs that meet the 0.4 reliability threshold and the mean reliability for TINs and TIN/NPIs at our proposed case minimum for each of the episode-based measures. We previously established at § 414.1350(c)(4) a case minimum of 10 episodes for procedural episode-based measures and at

[209] Mathematica, Inc., ''Memorandum: Reporting Period and Reliability of AHRQ, CMS 30-Day and HAC Quality Measures—Revised,'' *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

[210] Portney, L.G. and Watkins, M.P. (2000) Foundations of clinical research: Applications to practice. 2nd Edition, Prentice Hall Health, Upper Saddle River.

[211] Landis, J. Richard, and Gary G. Koch. ''The Measurement of Observer Agreement for Categorical Data.'' Biometrics 33, no. 1 (1977): 159–74. Accessed March 17, 2021. doi:10.2307/2529310.

[212] Koo, Terry K., and Mae Y. Li. ''A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research.'' Journal of Chiropractic Medicine 15, no. 2 (2016): 155–63. *https://doi.org/10.1016/j.jcm.2016.02.012.*

[213] Adams, J.L., Mehrotra, A., Thomas, J.W. and E.A. McGlynn, ''Physician Cost Profiling—Reliability and Risk of Misclassification,'' New England Journal of Medicine 362 (2010), 1014–21.

[214] Adams, John L., The Reliability of Provider Profiling: A Tutorial. Santa Monica, CA: RAND Corporation, 2009. *https://www.rand.org/pubs/technical_reports/TR653.html.*

[215] Taber, Keith S. ''The Use of Cronbach's Alpha When Developing and Reporting Research Instruments in Science Education.'' Research in Science Education 48, no. 6 (2017): 1273–96. *https://doi.org/10.1007/s11165-016-9602-2.*

[216] The Department of Education provides the following thresholds: ''Reliability of an outcome measure may be established by meeting the following minimum standards: (a) Internal consistency (such as Cronbach's alpha) of 0.50 or higher; (b) temporal stability/test-retest reliability of 0.40 or higher; or (c) inter-rater reliability (such as percentage agreement, correlation, or kappa) of 0.50 or higher.'' (What Works Clearinghouse (WWC) Standards Handbook v4, p.78).

[217] The National Quality Forum (NQF) reviews measures on a case-by-case basis, and has endorsed many types of measures with reliability ranging from below 0.1 and above 0.9, accepting multiple varied reliability testing methods. For example, NQF endorsed the Percent of Residents Who Lose Too Much Weight (NQF #0689) facility-level outcome measure, which had a signal-to-noise ratio of 0.078. Alternatively, NQF has also endorsed the Routine Cataract Removal with Intraocular Lens (IOL) Implantation (NQF #3509) episode-based cost measure with a mean reliability score of 0.94 at the individual clinician level and a 10 episode case minimum.

[218] See for example Sandhu AT, Do R, Lam J, et al. Development of the Elective Outpatient Percutaneous Coronary Intervention Episode-Based Cost Measure. Circ Cardiovasc Qual Outcomes. Mar 2021;14:e006461.

§ 414.1350(c)(5) a case minimum of 20 episodes for acute inpatient medical condition episode-based measures in the CY 2019 PFS final rule (83 59773 through 59774). For both the proposed Melanoma Resection procedural measure and the Sepsis acute inpatient medical condition measure, we found that the mean reliability for groups and individual clinicians exceeds 0.4 and that the majority of groups and individual clinicians meet the 0.4 reliability threshold when applying the established case minimum for the respective measure types. For the Colon and Rectal Resection procedural measure, at the established 10-episode case minimum for procedural measures, we found that the mean reliability does not exceed 0.4 for individual clinicians and that the majority of groups and individual clinicians do not meet the 0.4 reliability threshold. However, as displayed in Table 42, when the measure's case minimum is raised to 20 episodes, the mean reliability exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. As such, we propose to raise the case minimum for the Colon and Rectal Resection procedural measure to 20 episodes, and corresponding revisions to § 414.1350(c)(4). For the chronic condition measures, we propose at § 414.1350(c)(6), a case minimum of 20 episodes. At a 20-episode case minimum, the mean reliability for both measures exceeds 0.4 for both groups and individual clinicians, and the majority of groups and individual clinicians meet the 0.4 reliability threshold. We believe that calculating the episode-based measures with these case minimums would accurately and reliably measure the performance of a large number of clinicians and clinician group practices.

TABLE 42: Percent of TINs and TIN/NPIs that Meet 0.4 Reliability Threshold

Measure name (case minimum)	% TINs meeting 0.4 reliability threshold	Mean reliability for TINs	% TIN/NPIs meeting 0.4 reliability threshold	Mean reliability for TIN/NPIs
Asthma/COPD (20 episodes)	88.23%	0.67	81.66%	0.60
Colon and Rectal Resection (20 episodes)	91.57%	0.56	76.10%	0.45
Diabetes (20 episodes)	82.51%	0.61	78.80%	0.57
Melanoma Resection (10 episodes)	100.00%	0.82	100.00%	0.80
Sepsis (20 episodes)	100.00%	0.68	79.89%	0.47

(c) Proposed Process for Cost Measure Development by Stakeholders

(i) Background

Since 2017, we have conducted extensive stakeholder engagement to develop episode-based measures that cover a wide range of procedures, conditions, and specialties. This measure development process, as described in the CY 2019 PFS final rule (83 FR 59770), involves the measure development contractor convening hundreds of clinician experts to provide information to prioritize, conceptualize, and specify clinically refined cost measures and conducting national field testing on an 18-month timeline. The process involves engagement activities conducted by the measure development contractor to solicit expert input for measure development, gather feedback from individuals with lived experiences of the conditions in question, and collect stakeholder feedback on draft measure specifications that can inform how the measures can be improved. This approach follows CMS' standardized approach for developing, implementing, and maintaining measures. There are currently 18 episode-based measures in the cost performance category (CY 2020 PFS final rule (84 FR 62979)) with 5 more proposed to be added in this rule. There are also 2 global or population-based measures, the Medicare Spending per Beneficiary Clinician measure and the total per capita cost measure which were most recently refined in the CY 2020 PFS final rule (84 FR 62969 through 62977).

Many stakeholders have expressed support for episode-based measurement and for a process that prioritizes clinician involvement (as noted in the CY 2018 QPP final rule (82 FR 53645)). In the CY 2021 PFS final rule (85 FR 84879), we noted that commenters expressed interest in expanding the limited inventory of cost measures available to assess cost performance applicable to specialties. Commenters believed that additional episode-based measures would address gaps in cost performance assessment for various specialties. Expanding the range of procedures, conditions, and specialties would enable more MIPS eligible clinicians from different specialties and sub-specialties to have their cost performance assessed under clinically relevant episode-based measures. An increase in the range of cost measures available in MIPS that can be linked with quality measures and improvement activities in future MVPs would support the assessment of clinician value in providing specific types of care.

A process outside of the current development process that would allow stakeholders to develop cost measures could expand the inventory of episode-based measures. However, this process must ensure that any cost measures developed are consistent with the goals of MIPS, align with CMS priorities, and consistent with the Meaningful Measures Framework (more information

about the Meaningful Measures Framework can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*). Episode-based measures developed by stakeholders that meet the standards and criteria we propose below for selecting measures would contribute to the target of an estimated 50 percent of expenditures under Parts A and B, as described in section 1848(r)(2)(D)(i)(I) of the Act.

We propose to establish a process, beginning in CY 2022, for the development of cost measures by stakeholders that would ensure that the cost performance category has consistency across measures. The sections below outline the proposals for the measure prioritization criteria, standards for measure construction, pre-rulemaking submission process and development support, which altogether would comprise our proposed process of cost measure development by stakeholders.

(ii) Measure Prioritization Criteria

As described in section IV.A.3.d.(2)(b)(ii) of this rule, the current process for prioritizing cost measures for development involves the measure development contractor identifying candidate clinical areas and episode groups informed by a TEP, patient and family engagement perspective, and clinician stakeholders. Criteria reflecting TEP input have guided strategic decisions and informed clinical subcommittees' considerations for measure prioritization. These criteria include:

- Clinical coherence of measure concept (to ensure valid comparisons across clinicians).
- Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage).
- Opportunity for performance improvement.
- Alignment with quality measures and improvement activities to ensure meaningful assessments of value.

To inform cost measure development by stakeholders, we propose to apply these criteria to an environmental scan to identify a list of priority areas and suggested measures for development. This would ensure that measures developed by stakeholders align with program needs, while also providing flexibility for stakeholders to apply their own clinical expertise when identifying the most important areas for value improvement within the criteria listed above. Stakeholders who choose to develop cost measures can access the Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint* and the Meaningful Measures Framework at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page* for further information.

We seek public comment on the proposed measure prioritization criteria, as well as priority areas for future episode-based measure development, such as specialties, types of clinical care, or specific conditions or procedures that would support proposed or future MVPs.

(iii) Standards for Measure Construction

Our current rigorous cost measure development process has included a series of standards that ensure measures are effective in assessing clinician cost performance within MIPS. These standards have been developed and vetted over time by a standing TEP and further refined through discussions with clinical subcommittees and clinician expert workgroups convened by the measure development contractor around areas of care and specific measures, respectively. For further detail, we refer readers to our detailed discussion of the measure development process and framework in response to stakeholder comments in the CY 2019 PFS final rule (83 FR 59770). To ensure that cost measures developed by stakeholders meet the same standards applied during the current measure development and testing process, we propose to apply the following standards when considering stakeholder developed measures:

- Measures must assign services that accurately capture the role of attributed clinicians.
- Measures must have clear, ex ante attribution to clinicians.
- Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards.
- Measures' construction methodology must be readily understandable to clinicians.
- Measures must hold clinicians accountable for only the costs they can reasonably influence.
- Measures must convey clear information on how clinicians can alter their practice to improve measured performance.
- Measures must demonstrate variation to help distinguish quality of care across individual clinicians.
- Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data.

To implement these standards and to meet the methodology requirements of section 1848(r)(5) of the Act, we believe that it is necessary to ensure that measures within the cost performance category are consistent and share the same key features. Specifically, cost measures must be based on a standard set of measure components informed by the standards outlined above. These include: (1) Episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment.

Regarding item (1) episodes must be defined based on trigger codes for services, which are identifiable on Medicare claims, indicate the occurrence of the episode, and determine the patient cohort. Trigger codes must be based on services, and can incorporate diagnosis and other service information to define an episode. The patient cohort may be stratified into mutually exclusive stratifications (or ''episode sub-groups'') for meaningful clinical comparison to ensure that measures fairly compare clinicians with similar patient case-mix. Regarding item (2), episodes must be attributed to MIPS eligible clinician groups and clinicians who render the trigger services and are responsible for the patient's care and management. It is important that the attribution methodology allows for the most appropriate clinicians who have a significant role in a patient's care to be attributed and receive actionable feedback on their performance. Regarding item (3), all services that are clinically related to the attributed clinician's role in managing patient care must be included. This includes cases where the clinician can influence the frequency or intensity of services. The measure must include enough services to allow the measure to demonstrate that it captures variation in clinician performance. To address any potential concern around care stinting, the measure must cover a sufficiently long timeframe and broad enough services to capture downstream services. This includes expected follow-up care, rehabilitation, post-acute care (required if inpatient hospitalizations are included) and other support services, as well as complications, readmissions, and other consequences of care. Clinically unrelated services must not be assigned to the measure. Regarding item (4), measures must include applicable exclusions, which can be applied to the patient cohort or the episodes. Certain patients must be

excluded for data cleaning or to ensure completeness of data. For example, patients who do not have Medicare as their primary payer or were not continuously enrolled in Medicare Parts A and B and not C must be excluded as we would not be able to observe their complete care. Certain episodes must be excluded to improve episode homogeneity and to remove unique groups of patients from the measure in cases where it may be impractical or unreasonable to compare the costs of caring for these patients to the costs of caring for the measure cohort as a whole. Regarding item (5), measures must be adjusted for patient risk. Risk adjustment aims to isolate variation in clinician costs to only the costs that clinicians can reasonably influence by accounting for risk factors. The determination of an appropriate risk adjustment approach should be based on empirical testing. A base risk adjustment model must include standard risk adjustors (Hierarchical Condition Category [HCC] codes, interaction variables for certain comorbidities, age, disability status, end-stage renal disease status, recent use of institutional long-term care), as well as additional measure-specific risk factors. Finally, measures must include payment standardized claims data.

We have outlined in section IV.A.3.d.(2)(b)(iv) of this proposed rule a new methodological framework for assessing the cost of care for chronic conditions. This new chronic condition framework meets all the standards we outline above, and could serve as a basis for chronic condition measures developed by stakeholders that would ensure consistency with other MIPS measures. We propose to apply the standards for measure construction and measure components outlined above when considering stakeholder-developed measures to ensure that these measures follow the same standards as cost measures currently used in MIPS.

We seek public comment on our proposed standards for measure construction and measure components, as well as the challenges that stakeholders may encounter in the development of cost measures along with any resources that would assist stakeholders in development.

(iv) Cost Measure Submission to the Measures Under Consideration (MUC) List and Development Support

We propose that cost measures developed by stakeholders for potential use in MIPS would undergo the pre-rulemaking process described in section 1890A(a) of the Act. More details on the pre-rulemaking process can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.* As with the process for the call for quality measures, we propose that the submission process for cost measures developed by stakeholders would begin with a Call for Cost Measures, where stakeholders would be invited to submit their candidate cost measures. We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53635 through 53637) for details on the process for quality measure submissions and selection. During the Call for Cost Measures period, we would organize webinars and office hours to provide stakeholders with information about the process and be available to answer questions. We would also provide templates of written materials, such as the measure codes lists for stakeholders to use. At the end of this period, stakeholders would submit their candidate measures for review by completing the required data fields required for submission to the MUC list and if approved, measures would be placed on the final MUC List, which we publicly post on December 1 of every year. Measures submitted to the MUC List must be fully specified and tested for reliability and validity.

Submissions to the MUC list must include all required information and would be reviewed against a set of inclusion criteria identified below to determine whether they should be considered for use in MIPS. The inclusion criteria for cost measures developed by stakeholders are based on the criteria outlined in the MUC List submission template as well as relevant criteria that the MIPS quality performance category follows as indicated in the CY 2020 PFS final rule (84 FR 62953 through 62954). For purposes of our review, we propose that stakeholders who wish to submit measures must submit measure specification information, testing results, and related research to address the following inclusion criteria:

- *Applicable:* There is clinical coherence and comparability in clinician treatment; measures ensure alignment with quality indicators.
- *Feasible:* Measures use Medicare claims data; there is a high degree of data completeness and limited frequency of missing data.
- *Scientifically acceptable:* Measures are clinically valid assessments of cost performance; testing is available for reliability at different case minima; beta testing and statistical testing are conducted.
- *Not be duplicative of existing measures:* Measures assess opportunities and gaps based on CMS priorities and goals; there is an assessment of duplicate measures to see which would be the better measure.
- *Fully developed:* Measures are fully developed and ready for implementation at the time of submission.
- *Consistent:* The measure is constructed using a methodology to assess resource use that is consistent with sections 1848(r)(2) through (5) of the Act, consistent with other MIPS cost measures.
- *Fulfill a clinical performance gap:* Environmental scans and literature reviews show evidence for measures, performance gaps, and opportunities for improvement; there is evidence for measures' impact and importance to MIPS.

We seek comments on this proposed approach, and challenges stakeholders may encounter in the development of cost measures.

(d) Substantive Changes Criteria for Cost Measures

On an annual basis, we review the MIPS measures that have been adopted and consider updates to the cost measures. Changes to measures are an important part of the measure maintenance process to ensure that measures are continuing to function as intended, and may be substantive or non-substantive. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive changes to quality measures to be proposed and identified through notice-and-comment rulemaking. Although this section of the Act does not establish this requirement for cost measures, we believe that similar considerations should apply to cost measures. As discussed in prior rulemaking, examples of non-substantive changes to cost measures include maintenance changes such as updated diagnosis or procedure codes or changes to existing exclusions to the patient populations or definitions, while substantive changes to a measure are changes that result in what are considered new or different measures (83 FR 59767 and 84 FR 62961). As we evaluate existing cost measures to determine whether such measures need to be updated, we believe that it is important to establish criteria for determining whether a measure change is substantive. Thus, we are proposing to establish several criteria for determining whether a cost measure change is substantive starting with the 2022 MIPS performance period. The criteria include, but are not limited to, the following:

• Whether the change modifies the premise and/or objective of the measure;
• Whether the change modifies the scope of the measure (such as patient population eligible for the measure or a new category of costs); and
• Whether the change to the measure calculation significantly impacts how a measure is assessed.

Certain changes to a measure may affect multiple elements of a measure, requiring an overall assessment of the measure specifications. The following are some examples of potential substantive and non-substantive changes:

• *Measure objective:* The measure objective refers to what is being assessed; in general, changes to the measure objective would be considered substantive. The question of what is being assessed can generally be thought of as: What type of care is the measure assessing, who is providing this care, and who is in the patient cohort. Specifically, under this criterion, a change to the measure objective could include updates to the triggering logic, measure exclusions, attribution rules, or other aspects of the specifications. While the effect of such updates may also be relevant while considering whether the change is substantive or not, the effect is secondary to the intention behind changes to the measure. Consider the following example: A hypothetical episode-based measure focuses on major joint repair, and is updated to cover all joint procedures by adding a range of trigger codes. This likely would be a substantive change, as the measure would be evaluating different joints and procedures than the initial measure objective.

• *Types of Costs being Assessed:* In general, new rules about which costs are being captured by a measure would be considered substantive if they change which categories or types of costs are included in a measure, and non-substantive if they merely refine how an existing category is captured. For example, a change to an episode-based measure's service assignment rules which adds a new category of costs (for example, adding Part D costs to a measure that did not previously include any Part D costs) likely would be a substantive change. By contrast, a measure update to reflect new codes for existing types of codes, for instance, where a code is split into sub-codes for greater granularity, likely would be considered non-substantive.

• *Risk Adjustment:* The purpose of risk adjustment is to account for factors outside of the clinician's or clinician group's reasonable influence. In certain cases, it is necessary to make changes to the risk adjustment model and/or individual risk adjustors to ensure that the risk adjustment approach is working as intended. Generally, changes to risk adjustment variables and the mechanics of the regression would be considered non-substantive, if they continue to give effect to the measure's intent. However, some changes to the risk adjustment approach may be substantive, such as changes to the type of risk adjustors used (for example, the addition of non-claims-based variables when the model previously only used claims-based data), or changes to the stratification that modify the interpretation of what the measure score represents.

We note that there are degrees in any evaluation of whether a change is substantive. For instance, there may be important differences in the effect of adding one service or code compared to a suite of services and codes that we would also consider as part of determining whether a change is substantive or not. We believe the proposed substantive change criteria for cost measures would help us to determine whether a change to a cost measure should be made through notice-and-comment rulemaking before it is implemented in MIPS. We seek public comment on our proposed criteria for determining whether a change to a cost measure is substantive.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 through 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), and the CY 2021 PFS final rule (85 FR 84881 through 84886). We also refer readers to 42 CFR 414.1305 for the definition of improvement activities and attestation, § 414.1320 for the performance period, § 414.1325 for the data submission requirements, § 414.1355 for the improvement activity performance category generally, § 414.1360 for data submission criteria, and § 414.1380(b)(3) for improvement activities performance category scoring.

In this proposed rule, beginning with the CY 2022 performance period and future years, we propose: (1) To revise group reporting requirements for the 50 percent threshold to address subgroups; (2) to revise timeframe for improvement activities nominated during a public health emergency; (3) to revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (4) to suspend activities that raise possible safety concerns or become obsolete from the program when this occurrence happens outside of the rulemaking process; (5) to add 7 new improvement activities, modify 15 existing improvement activities, and remove 6 previously adopted improvement activities for the CY 2022 performance period and future years; (6) to revise the ''Drug Cost Transparency to include requirements for use of real-time benefit tools'' improvement activity; and (7) to add the COVID–19 ''Clinical Data Reporting with or without Clinical Trial'' improvement activity for CY 2022 performance period and future years.

(b) Group Reporting

In the CY 2020 PFS final rule (84 FR 62981 through 62988), we revised § 414.1360(a)(2) to state that, beginning with the 2020 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs billing under the group's TIN or virtual group's TINs, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

In the CY 2021 PFS final rule (85 FR 84844 through 84849), we finalized to update the MIPS Value Pathways guiding principle #2 as follows: ''2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.''

In this proposed rule, we are proposing the details of subgroup reporting for MVPs. We refer readers to section IV.A.3.b. of this proposed rule for further details. In order to implement group requirements in relation to subgroup reporting, we need to modify our policy regarding group reporting for improvement activities. We continue to believe that a 50 percent threshold is achievable and appropriate because, if a group or virtual group has implemented an improvement activity, the activity should be recognized and adopted throughout much of the practice to improve clinical practice,

care delivery, and outcomes. Similarly, we believe that it makes sense to allow subgroups to perform and attest to their improvement activities separately and apply the 50 percent threshold within their subgroup. Our policy codified at § 414.1360 does not currently include a subgroup option. Therefore, we are proposing to revise § 414.1360(a)(2) to state that, beginning with the 2022 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

We receive many inquiries through the Quality Payment Program help desk requesting clarification on how to apply the 50 percent threshold to groups. Many commenters requested that their groups be allowed to account for the 50 percent threshold by specialty or as a subgroup as they have more in common when considering applicable improvement activities. The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1–866–288–8292 (Monday–Friday 8 a.m.–8 p.m. ET) or email *QPP@cms.hhs.gov.* We believe the ability to attest to improvement activities at the subgroup level responds to this stakeholder concern, as this proposal, if finalized, would allow eligible clinicians the ability to compose subgroups by specialty for reporting MVPs.

For example, if a TIN that includes 100 clinicians and decides that they will be participating in MIPS as a group, at least 50 percent (in this example, at least 50 clinicians) would need to attest to the same improvement activity for a continuous 90 days within the current performance year. However, if among this group, there are 30 clinicians that represent the orthopedic specialty, they may decide to form a subgroup to report measures and activities, more closely linked to their improvement goals. We refer readers to section IV.A.3.b. of this proposed rule for requirements when forming a subgroup. If the 30 clinicians that represent the orthopedic specialty register as a subgroup, at least 15 of these orthopedic clinicians would be required to complete an improvement activity for the required performance period at some point during the performance year to receive full credit for the subgroup. The 70 clinicians from the original group would need at least 50 percent (in this example, at least 35 clinicians) to complete a given improvement activity for this group to receive credit for the improvement activity.

We request public comments on our proposal.

(c) Improvement Activities Inventory

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory (81 FR 77817 through 77830) consisting of approximately 95 activities. We took several steps to ensure the Inventory was inclusive of activities in line with statutory and program requirements. We discussed that we had numerous interviews with highly performing organizations of all sizes, conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category, including the patient-centered medical homes, the Transforming Clinical Practice Initiative (TCPI), CAHPS surveys, and AHRQ's Patient Safety Organizations. In addition, we reviewed the CY 2016 PFS final rule with comment period (80 FR 70886) and the comments received in response to the MIPS and APMs RFI regarding the improvement activities performance category.

For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

(A) Timeframe for the Annual Call for Activities

We refer readers to the CY 2019 PFS final rule (83 FR 59781 through 59782) for our most recent policies with respect to the timeframe for the Annual Call for Activities. We are not proposing any changes to this policy in this proposed rule. However, we refer readers to section IV.A.3.d.(3)(c)(i) of this proposed rule where we are proposing changes to the timeframe for nominating new improvement activities during a public health emergency.

(B) Proposed Changes for Nominating New Improvement Activities

As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77190), the initial improvement activities Inventory was not based on the established criteria; rather, it was compiled via stakeholder input, an environmental scan, MIPS and APMs RFI comments, and subsequent working sessions with AHRQ and ONC and additional communications with CDC, SAMHSA, and HRSA. In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory that included establishing the required criteria. In the CY 2019 PFS final rule (83 FR 59778 through 59779), we adopted 1 new criterion and removed a criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities. In this proposed rule, we are proposing: (1) Changes to the timeframe for improvement activities nomination during a public health emergency (PHE); (2) 2 new improvement activities criteria; (3) to increase the minimum required minimum number of criteria that must be met for improvement activities nominations; and (4) to separate required from optional criteria for improvement activities nominations. These proposals are discussed in detail in section IV.A.3.d.(3)(c) of this proposed rule.

(aa) Proposed Changes to the Timeframe for Nominating New Improvement Activities During a Public Health Emergency

In the CY 2021 PFS final rule (85 FR 84882 through 84883), we finalized an exception stating that during public health emergencies (PHE) stakeholders

can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through July 1 each year, we adopted a policy to accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process was affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). We noted that we continue to believe it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity related to the PHE considered for inclusion in the Inventory would need be finalized through rulemaking.

In 2020, we used several interim final rules with comment period (IFCs) to propose necessary policies due to the PHE for COVID–19, including adding and modifying the COVID–19 Clinical Data Reporting with or without Clinical Trial (IA_ERP_3) for implementation in the same year. However, we want to be clear that we are not limited to IFCs and those vehicles may not be the most timely or feasible for a particular situation. In a typical year, we use various fiscal and calendar year rules to implement policy (for example, the IPPS, Inpatient Psychiatric Facility Prospective Payment System (IPF PPS), OPPS, etc. rules). In order to best operationalize our policy for improvement activities nominated during a PHE, we are proposing to modify our policy such that these nominations should be submitted by January 5th, of the year in which the activity is targeted for implementation unless otherwise specified by CMS, in order to maximize the chance that a potential improvement activity could be implemented in the same year via the most timely rulemaking vehicle.

We request public comments on this proposal.

(bb) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders should apply 1 or more of the below criteria when submitting nominations for improvement activities (82 FR 53660). In addition, in the CY 2019 PFS final rule (83 FR 59779) we finalized to add a ''public health emergency as determined by the Secretary'' and in the CY 2021 PFS final rule (85 FR 84883 through 84884) we finalized to add ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' to the criteria below.

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

(cc) Proposed 2 New Criteria

In addition to the aforementioned considerations, when considering improvement activities for possible inclusion in MIPS, we propose 2 new criteria beginning with the CY 2022 Annual Call for Activities MIPS improvement activities: (1) Should not duplicate other improvement activities in the Inventory; and (2) should drive improvements that go beyond standard clinical practices. Regarding the first proposed criterion, we believe that there should not be duplication in the Inventory as clinicians could get double credit for doing the same activity. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77185), while the minimum reporting period for one improvement activity is 90 days, the maximum frequency with which an improvement activity may be reported would be once during the 12-month performance period. It is important that stakeholders review the current Inventory to ensure there is not a broader improvement activity that clinicians could attest to for the same activity. Regarding the second proposed criterion, we believe that improvement activities should drive improvements that go beyond standard clinical practices and should be innovative, to have the potential for significant patient benefit when clinicians learn and implement the activities.

We request public comments on our proposals.

(dd) Proposed Minimum Requirement

We have received feedback from stakeholders through the Annual Call for Activities process and during the CY 2021 PFS rulemaking process that the nomination acceptance process is unclear, stakeholders are frustrated by nominating improvement activities that are not accepted, and our reasoning for not accepting their nomination is not clear.

Our current policy requires that stakeholders apply a minimum of 1 or more of the established criteria when submitting a nomination through the Annual Call for Activities process for a new improvement activity (82 FR 53660). Through past Annual Call for Activities, we have found that many of the nominations that we receive meet the minimum 1 criterion, but are not appropriate for inclusion in the Inventory for other reasons. We often receive submissions describing practices that are standard and submissions that are too specific to a particular specialty. We believe that when evaluating nominations, we should use multiple factors in deciding on the selection of submitted improvement activities, not all of which can be listed upfront. Ultimately, we must rely on our internal processes and expertise in determining whether or not a nominated improvement activity meets the criteria and needs of the program. However, in an effort to increase transparency, we have reevaluated our criteria and believe there are a number of significant criteria that improvement activity proposals should meet to be included in the Inventory. Therefore, beginning with nominations submitted during the 2022 nomination period for the Annual Call for Activities, we are proposing to increase the number of criteria stakeholders are required to meet when submitting an activity proposal, from a minimum of 1 to 8 criteria, which includes the 2 proposed criteria in section IV.A.3.d(3)(c)(i)(B)(cc) of this proposed rule should they be finalized.

We believe that the following 8 criteria, 6 of which are on the current list and 2 of which are proposed (in

italics), should be the foundation for all improvement activities:

1. Relevance to an existing improvement activities subcategory (or a proposed new subcategory) (82 FR 53660);

2. Importance of an activity toward achieving improved beneficiary health outcomes (82 FR 53660);

3. Feasible to implement, recognizing importance in minimizing burden, including, to the extent possible, for small practices, practices in rural areas, or in areas designated as geographic Health Professional Shortage Areas (HPSAs) by the Health Resources and Services Administration (HRSA) (82 FR 53660);

4. Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes (82 FR 53660);

5. Can be linked to existing and related MIPS quality, Promoting Interoperability, and cost measures as applicable and feasible (85 FR 84884);

6. CMS is able to validate the activity (82 FR 53660);

7. *Does not duplicate other improvement activities in the Inventory;* and

8. *Should drive improvements that go beyond purely common clinical practices.*

While we previously finalized the first 6 criteria in prior rulemakings, we did not specifically require all. We are seeking to minimize improvement activity nominations that do not meet program standards, and to increase nominations that will substantively contribute to improved patient care and outcomes.

In crafting this proposal, we also considered whether any of the above proposed required criteria should be optional instead (see proposal in the next section (IV.A.3.d(3)(c)(i)(B))). Ultimately, we proposed the above criteria as required, because we believe these reflect the minimum standard for improvement activities in the Inventory and would help increase transparency in our decisions.

We request public comments on our proposal. In addition, for future rulemaking, we also request comment on any other potential required criteria that should be considered for future adoption.

(ee) Proposed Optional Factors

Additionally, we are proposing the remaining 6 previously established factors would serve as optional factors beginning with nominations submitted during the 2022 nomination period for the Annual Call for Activities, as we believe they may be relevant to certain nominations, but not all. Meeting 1 or more of the optional factors may increase a nomination's chances of being added to the Inventory. The proposed optional factors are:

1. Alignment with patient-centered medical homes (82 FR 53660);

2. Support for the patient's family or personal caregiver (82 FR 53660);

3. Responds to a public health emergency as determined by the Secretary (83 FR 59779);

4. Addresses improvements in practice to reduce health care disparities (82 FR 53660);

5. Focus on meaningful actions from the person and family's point of view (82 FR 53660); and

6. Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care) (82 FR 53660).

We request public comments on our proposal.

(C) Improvement Activity Removal

In the CY 2020 PFS final rule (84 FR 62988 through 62990), we finalized the factors for consideration in removing improvement activities. We stated that we would fully examine each activity prior to removal and that commenters would have an opportunity to provide their input during notice-and-comment rulemaking.

(aa) Proposed Improvement Activity Suspension Policy

A circumstance has come to our attention that requires we examine the specifics of the improvement activities removal of activities policy in relation to the performance period. Following the publication of the CY 2021 PFS proposed rule, we became aware that the underlying program for 1 of the improvement activities in the Inventory had expired on March 31, 2020. Therefore, clinicians could no longer complete the activity from April 1 through December 31, 2020. To avoid any potential confusion or incorrect attestation, we removed this activity in the CY 2021 PFS final rule (85 FR 84885). This occurrence alerted us to the potential that other activities could become obsolete or be impacted by clinical practice guideline changes that affect the activity and could potentially result in patient harm, and that we may not learn about this information during the rulemaking timeframes. Because changes made in rulemaking do not apply until the following performance year, this timing could affect an improvement activity that needs to be urgently addressed.

As a result, beginning with the 2022 performance period, we are proposing that in the case of an improvement activity for which there is a reason to believe that the continued collection raises possible patient safety concerns or is obsolete, we would promptly suspend the improvement activity and immediately notify clinicians and the public through the usual communication channels, such as listservs and Web postings. We would then propose to remove or modify the improvement activity as appropriate in the next rulemaking cycle.

We request public comments on our proposal.

(ii) Changes to the Improvement Activities Inventory

(A) Background

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538), and Tables A, B, and C in the Appendix 2 of the CY 2021 PFS final rule (85 FR 85370 through 85377) for our previously finalized improvement activities Inventory. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvement Activities&py=2020* for a complete list of the current improvement activities. In this proposed rule, we are proposing to add 7 new improvement activities, modify 15 existing improvement activities, and remove 6 previously adopted improvement activities for the CY 2022 performance period and future years. We refer readers to the below and Appendix 2 of this proposed rule for more details.

(B) Proposed Changes to Adopted Improvement Activities

(aa) Proposed Changes to the ''Drug Cost Transparency To Include Requirements for Use of Real-Time Benefit Tools'' Improvement Activity

In the CY 2020 PFS final rule (84 FR 63515), we adopted IA_BE_25, titled ''Drug Cost Transparency to include requirements for use of real-time benefit

tools'' beginning with the 2020 performance year and for subsequent years. This activity description reads as follows: To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s)). Thus, this activity allows a real-time benefit tool (RTBT) to be one source of information for pricing of pharmaceuticals, which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary.

The 2021 Consolidated Appropriations Act (H.R. 116–133, Pub. L. 116–260) B included section 119 in Division CC entitled ''Increasing the use of real-time benefit tools to lower beneficiary costs.'' Subsection (c) of section 119 includes a provision called ''Inclusion of Use of Real-Time Electronic Information in Shared Decision-Making Under MIPS.'' This provision amended section 1848(q)(2)(B)(iii)(IV) of the Act by adding text noting that this subcategory shall include as an activity, for performance periods beginning on or after January 1, 2022, use of a real-time benefit tool as described in section 1860D–4(o) of the Act. In addition, the Secretary may establish this activity as a standalone or as a component of another activity.

In accordance with this statutory requirement, in this proposed rule, we propose to modify this improvement activity such that beginning with the CY 2022 performance year and for subsequent years, the activity would require use of an RTBT. As previously finalized, use of an RTBT was optional. We refer readers to Appendix 2 of this proposed rule for additional details.

We request public comments on our proposal.

(bb) Proposed Changes to the COVID–19 Clinical Data Reporting With or Without Clinical Trial (IA_ERP_3) Improvement Activity

We refer readers to the March 31st IFC for COVID–19 (85 FR 19276 through 19277) and September 2nd COVID–19 IFC (85 FR 54848 through 54851) for a regulatory history of this improvement activity. In the September 2nd COVID–19 IFC (85 FR 54848 through 54851), we extended the modified COVID–19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the continued COVID–19 infection we were experiencing nationwide. We anticipated the need for COVID–19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we would reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed.

In this proposed rule, we are proposing to extend the COVID–19 Clinical Data Reporting with or without Clinical Trial improvement activity for CY 2022 performance period and future years due to continued COVID–19 infections we are experiencing nationwide and the need for further research. Clinicians will continue to treat beneficiaries with COVID–19, and we anticipate the need for COVID–19 clinical trials and data collection/sharing through registries to continue through CY 2022 and future years. Each year, we intend to reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We believe it is important for eligible clinicians to be able to attest to this improvement activity if it is still pertinent. Further, we believe that participation in this improvement activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID–19. We will continue to reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed and would discontinue the activity through notice-and-comment rulemaking as needed. We also refer readers to Appendix 2 of this proposed rule for details on our proposals to add 7 new improvement activities, modify 15 previously adopted improvement activities, and remove 6 previously adopted improvement activities.

We request public comments on our proposal.

(4) Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record technology (CEHRT) as a performance category under the MIPS. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2021 PFS final rule at § 414.1320(g)(1) (85 FR 84886), for the 2024 MIPS payment year, and each subsequent MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2024 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of any continuous 90-day period within CY 2022, up to and including the full CY 2022 (January 1, 2022 through December 31, 2022). We stated that we believe this would be an appropriate performance period because it would offer stability and consistency for MIPS eligible clinicians reporting for the Promoting Interoperability performance category. We are not proposing any changes to the Promoting Interoperability performance category performance period that we established under § 414.1320(g)(1) (85 FR 84886).

(c) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Proposed Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

(A) Measure Background

We have adopted a Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing objective. For background

on this measure, we refer readers to the CY 2019 PFS final rule (83 FR 59800 through 59803) and the CY 2020 PFS final rule (84 FR 62992 through 62994). In the CY 2021 PFS final rule (85 FR 84887 through 84888), we finalized that the Query of PDMP measure will remain optional and eligible for 10 bonus points for the CY 2021 performance period/ 2023 MIPS payment year.

(B) State PDMPs' Progress and Previous Stakeholder Feedback

In the CY 2020 and CY 2021 PFS final rules (84 FR 62992 through 62994 and 85 FR 84887 through 84888), we described the concern expressed by stakeholders that they believed it was premature for the Promoting Interoperability performance category to require the Query of PDMP measure and score it based on performance. Feedback received from health IT vendors and MIPS eligible clinicians expressed that flexibility in the measure presents unintended challenges such as significant burden associated with IT system design and additional development needed to accommodate the measure and any future changes to it.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to specify a single approach to PDMP–EHR integration at this time. At the same time, we have heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These stakeholders stated that health IT developers may face significant cost burdens if they either fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Stakeholders have noted that the cost of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure (for public comments discussed in last year's final rule, we refer readers to 85 FR 84887 through 84888).

In support of efforts to expand the use of PDMPs, there are currently a number of federally supported activities underway aimed at developing a more robust and standardized approach to EHR–PDMP integration. federal partners, including the CDC and ONC, and private sector stakeholders, are focused on developing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck, which is a federally supported interstate exchange hub for PDMP data.[219] The ONC Interoperability Standards Advisory describes monitoring of current and emerging standards related to PDMP and opioid use disorder (OUD) data capture and exchange that would allow a provider to request a patient's medication history from a state PMDP and for PDMP data to be exchanged between systems and states.[220] We believe these standards and technical approaches are likely to rapidly reach maturity to support exchange across health care system stakeholders.

The SUPPORT for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, is an important investment in combating the opioid epidemic. Several of the provisions of the SUPPORT for Patients and Communities Act address opioid use disorder prevention, recovery, and treatment, including legislative changes specific to the Medicare and Medicaid programs intended to increase access to evidence-based treatment and follow-up care. Specifically, with respect to PDMPs, the SUPPORT for Patients and Communities Act included new requirements and federal funding for PDMP enhancement, integration, and interoperability, and established mandatory use of PDMPs by certain Medicaid providers to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorder beginning in October of 2021.

(C) Proposed Measure Changes

Given current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns about the current readiness across states for implementation of the existing measure, we believe that at least 1 more year is needed prior to potentially requiring the Query of PDMP measure.

While we appreciate the concerns that stakeholders have shared, we continue to believe that this measure can play an important role in helping to address the opioid crisis. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions. Maintaining it as an optional measure with bonus points signals to the MIPS eligible clinician and vendor community that this is an important measure to address a current gap that can help spur development and innovation in order to reduce barriers and challenges.

Therefore, we are proposing to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 10 bonus points for the CY 2022 performance period/2024 MIPS payment year. We seek comments on this proposal.

(D) Health IT Updates and Measure Direction

Given recent progress in a variety of areas, we believe that there is now a clearer trajectory forward to potentially requiring the Query of PDMP measure. These developments include updated requirements for certified health IT, standards development activities around PDMPs, and other projects which can more tangibly inform future policy changes. For example, under final policies recently adopted in the CY 2021 PFS final rule (85 FR 84815 through 84828), participants in the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) and the Promoting Interoperability performance category are scheduled to begin using certified EHR technology incorporating application programming interfaces (APIs) based on HL7® FHIR® standard version Release 4 in CY 2023 consistent with updates to certified health IT which were finalized in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (hereinafter referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961,

[219] *https://www.pdmpassist.org/RxCheck.*

[220] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

25740).[221] Updates to 2015 Edition health IT certification criteria in the ONC 21st Century Cures Act final rule also incorporated NCPDP SCRIPT standard version 2017071 for electronic prescribing. The availability of both standardized APIs and updated standards for e-prescribing within certified health IT could serve as a stepping stone to future technical approaches that enable more seamless exchange of data between CEHRT and PDMP systems.

A number of recent efforts have sought to improve interoperability between EHRs and PDMPs. In 2020, ONC completed work to map the NCPDP SCRIPT standard version 2017071, the Prescription Monitoring Information eXchange (PMIX) standard version 2, and the 2015 American Society for Automation in Pharmacy (ASAP) Prescription Monitoring Program Web Service standard version 2.1A to the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard version Release 4.

ONC also began work in partnership with the CDC, the Department of Justice's Bureau of Justice Assistance, and the eHealth Exchange to develop a prototype to pilot an innovative technical solution for the delivery of patient medication histories across state lines via HL7® FHIR®. The eHealth Exchange is a network of networks that is active in all 50 states connecting federal and non-federal healthcare organizations to improve patient care and public health. To date, the prototype has been successfully tested in several states. Early prototype testing used synthetic data to evaluate system capacity to send and receive a patient's medication history request and response. The goal of the project is to allow any provider who is live on the eHealth Exchange to use that existing connection to query a patient's record on the RxCheck Hub, which routes the query to individual state PDMPs who are also live on RxCheck. This solution will enable health care providers to query PDMPs via existing connections to health information exchange (HIE) networks as a way to: (1) Leverage existing technology; (2) reduce burden associated with multiple, disparate system interfaces and workflows; and (3) allow for the exchange and full integration of data within allowable law from the point of exchange for medication reconciliation, allergy checks, and other forms of clinical decision support.

[221] HL7® and FHIR® are registered trademarks of Health Level Seven International.

Based upon these developments, which are advancing enhanced certified functionality, effective functional data exchange, and the use of open, mature standards, we believe there is a much better informed roadmap for achieving better integration between PDMPs and EHRs with enhanced interoperability of controlled prescription data across states and systems. We believe that as these activities develop, they can help to address some of the previous concerns raised by stakeholders around this measure, and we will continue to work with ONC to monitor these activities.

While we believe the Query of PDMP measure is very important to avoid and address the over-prescribing of opioids, we also recognize that some states and systems may not be ready at this time to effectively exchange this data. In light of further work in this area and our stated goals for increasing the impact of this measure, we are seeking stakeholder comment on plans for requiring the Query of PDMP measure in the Promoting Interoperability performance category in the near future. To advance in this direction with both transparent proposals and informed guidance, we request public comment on the future direction for the measure, specifically:

- To what degree would all MIPS eligible clinicians be prepared to report on the current Query of PDMP measure (Yes/No response) in the near future? What additional considerations would need to be addressed before transitioning to a version of the measure that requires the submission of a numerator/denominator?
- Would changes to the Query of PDMP measure be necessary to accommodate other technical approaches that may be implemented in the future, such as exchange of information with a PDMP or with multiple PDMPs using HL7® FHIR®?
- What, if any, exclusions should be made available as part of the measure's specifications with regard to MIPS eligible clinicians?
- When will state PDMPs be ready to effectively exchange data with provider systems using HL7® FHIR® to support this measure? What are the most common standards and approaches used to access PDMP data through provider systems currently?
- What technical considerations exist for intrastate vs. interstate PDMP queries? How could health information exchange networks play a role in expanding access to PDMP data? In what ways could FHIR® applications be supported to safely share PDMP data within a clinician's workflow?

(ii) Proposed Changes to the Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

(A) Background

In the CY 2019 PFS final rule (83 FR 59812 through 59815), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective, which includes the Provide Patients Electronic Access to Their Health Information measure. For more information about the Provide Patients Electronic Access to Their Health Information measure, we refer readers to the following preamble discussions in prior rulemaking: 84 FR 62995 and 62999 through 63000, 83 FR 59812, 82 FR 53674, 81 FR 77228, 80 FR 62841 through 62851, 77 FR 54007, and 75 FR 44353.

(B) Proposed Data Availability Requirement for MIPS Eligible Clinicians

The Provide Patients Electronic Access to Their Health Information measure requires, for at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT (84 FR 62999–63000 and 82 FR 53674). We are proposing to modify this measure to require MIPS eligible clinicians to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT. MIPS eligible clinicians would be required to ensure this information remains available indefinitely (that is, not merely for a defined period of time). The proposed requirement would apply beginning with the performance period in 2022, and would include all patient health information from encounters on or after January 1, 2016.

Currently, the Provide Patients Electronic Access to Their Health Information measure does not specify how long MIPS eligible clinicians are required to make patient data available, or to ensure that patient data remain

available to patients in the event that a MIPS eligible clinician switches EHR vendors (81 FR 77228). In an effort to minimize stakeholder burden, we want to align the date under our proposal for making information about encounters available with the date of service start date (January 1, 2016) as finalized in the Patient Access and Interoperability final rule (85 FR 25528), and as proposed for the Promoting Interoperability Program for eligible hospitals and CAHs in the FY 2022 IPPS/LTCH proposed rule (86 FR 25631). As an alternative to our proposal, we considered different encounter start dates, such as encounters on or after January 1, 2012, or encounters on or after January 1, 2019. We believe, however, that a requirement for MIPS eligible clinicians to ensure patient health information remains available indefinitely, as well as an encounter start date of January 1, 2016, would provide the most benefit to patients when accessing their health information as compared to the burden and costs to MIPS eligible clinicians implementing these proposed requirements.

We are seeking public comment on our proposal to modify the Provide Patients Electronic Access to Their Health Information measure, as well as the alternatives we have considered.

(iii) Modifications to the Public Health and Clinical Data Exchange Objective

(A) Background

In the CY 2019 PFS final rule (83 FR 59795, 59815 through 59817), for the Public Health and Clinical Data Exchange Objective, we finalized that a MIPS eligible clinician must submit a yes/no response for two different public health agencies or clinical data registries for any of the five measures associated with the Public Health and Clinical Data Exchange objective (Syndromic Surveillance Reporting; Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; and Public Health Registry Reporting) to earn 10 points for the objective. Failure to report on two different public health agencies or clinical data registries or submitting a ''no'' response for a measure will earn a score of zero. If an exclusion is claimed for one measure, but the MIPS eligible clinician submits a ''yes'' response for another measure, they will earn the 10 points for the objective. If a MIPS eligible clinician claims exclusions for both measures they select to report on, the 10 points will be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

The Promoting Interoperability performance category for eligible clinicians has been an important mechanism for encouraging health care data exchange. But in an attempt to reduce burden, we previously stated our intention to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022 (83 FR 59816). Many commenters opposed this potential policy change and noted that interoperability of public health data is still evolving and incentivizes MIPS eligible clinicians to share data with public health agencies (83 FR 59816). In response to these comments, we stated that we will continue to monitor the data we compile specific to the public health reporting requirements and take the commenters' concerns into consideration related to future actions (83 FR 59816).

Effective responses to public health events, such as the COVID–19 pandemic, require fast, accurate exchange of data between health care providers and federal, state, and local public health agencies (PHAs). Health care providers collect these data for patient care and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

While our current approach has encouraged health care systems to stand up some of these capabilities, significant gaps remain, and absent stronger incentives it will be difficult to stand up the comprehensive data exchange needed for future public health response. Thus, we believe that a more assertive approach is needed.

(B) Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective

In this section, we are proposing to require two of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the performance period in CY 2022: Immunization Registry Reporting; and Electronic Case Reporting. These two measures would put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening two important public health functions: (1) Vaccine uptake; and (2) case surveillance. Requiring these measures would enable automated case reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies.

(aa) Immunization Registry Reporting Measure

Immunizations are considered one of the ten great public health achievements and have resulted in declines in cases, hospitalizations, deaths, and health care costs associated with vaccine preventable diseases.[222] The benefits and value of immunizations are realized when public policy, health systems, and community-based intervention efforts are working in coordination. Ensuring the coordination of these efforts can achieve high immunization coverage is dependent on the availability of timely, accurate, and complete information on vaccinations received by individuals in a population.

Immunization registries (also called immunization information systems, or IIS) are powerful tools that allow collaboration between vaccine providers and public health agencies and enable coordination of population-based interventions. Immunization registries are confidential, population-based, computerized systems that record all vaccination doses administered by participating health care providers for individuals residing within a particular jurisdiction. At the point of clinical care, an immunization registry can provide consolidated immunization histories to assist vaccine providers in determining appropriate patient vaccinations. At the population level, immunization registries provide data on vaccination coverage assessment and program operations and in guiding public health action to improve vaccination rates.

Currently, 50 states, the District of Columbia, eight island territories, and three cities (New York City, Philadelphia, and San Diego) operate an immunization registry. CDC provides technical assistance and nationwide leadership to all state immunization registries to ensure the optimal use of immunization registries for determining vaccination coverage at local, state, and national levels. Immunization registries already have connections in place to capture administered doses in real-time for a substantial portion of the population, a process accelerated over the last 10 years by the Medicare and Medicaid Promoting Interoperability Programs. According to data from the most recent CDC IIS Annual Report (2019) available, immunization registries currently hold demographics and immunization data on 95 percent of

[222] Ten Great Public Health Achievements—United States, 2001–2010 (*cdc.gov*).

children 0–6 years, 82 percent of adolescents, and 60 percent of adults.[223] While each state Immunization registry currently coordinates with health care providers and EHR systems to achieve interoperability and facilitate immunization reporting, varying state reporting policies limit the completeness and timeliness of records in immunization registries and the optimal use of immunization registries for determining vaccination coverage.

We are proposing to make the Immunization Registry Reporting a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the performance period in CY 2022 as it is critical for understanding vaccination coverage both at the jurisdiction level and nationwide and identifying where additional vaccination efforts are needed. For more information about the Immunization Registry Reporting measure, we refer readers to the preamble discussion in prior rulemaking at 81 FR 77230. Making standardized reporting to an immunization registry a required measure would provide an immediate benefit by increasing the COVID–19 vaccination records reported to these systems. Making the measure required would also improve the data quality of records in immunization registries and facilitate use of immunization registries for clinical decision support and tracking of vaccine administration and distribution.

We believe that making the Immunization Registry Reporting measure required would increase the reporting of immunization data by health care providers to public health agencies. Making the measure required is also critical for the COVID–19 vaccination response because it would provide a better view of the vaccines administered and distributed at national, state and local levels. This is a function immunization registries currently provide for all public vaccines, but is particularly important for COVID–19 vaccines. In addition to the COVID–19 vaccination response is the equally important need for routine vaccination coverage to increase. Fear of COVID–19 has caused deferrals of routine vaccinations as patients limit their interactions, including with their family doctors. More complete data in immunization registries as a result of the required measure would also optimize the use of immunization registries to determine who has not been vaccinated, pockets of under vaccination, and identifying where interventions should be focused for routine and emergency response vaccines. Requiring the measure would reduce the regulatory and administrative burden health care providers experience when exchanging information with immunization registries.

We are not proposing any changes to the description of the measure including any of the exclusions that we established in CY 2019 PFS final rule at 83 FR 59815 through 59817.

(bb) Electronic Case Reporting

Health care providers are required by state law to report certain diseases and conditions, a process called case reporting, which provides PHAs with data on approximately 120 diseases and conditions of public health significance.[224] Case reporting is a vital and longstanding tool that PHAs use to prevent the spread of infectious diseases. Case reporting serves as early notification to PHAs for potential outbreaks and includes information that enables PHAs to start contact tracing and other prevention measures. Case reports also include critical clinical information that would not be included in syndromic surveillance or laboratory reporting, and can help to illuminate the impact of comorbidities, treatments, and variable access to care. Information from the case reports can be used to further work on social determinants of health and ensure equal access to preventative care across populations. Electronic case reporting is the automated, real-time, bidirectional exchange of case report information between EHRs and PHAs. Electronic case reporting uses standard codes to trigger the transfer of relevant clinical data to PHAs for case investigation and follow-up. As of March 2021, most states do not require electronic submission of case reports as part of their regulations and case reporting often occurs through outdated manual methods (for example, fax, email, or phone), which results in delays, underreporting, and incomplete or inaccurate case data. Manual case reporting also imposes burdens on health care providers, taking staff time away from patients to submit case reports and comply with state reporting requirements. Electronic case reporting allows health care providers to fulfill mandated public health reporting requirements without imposing additional burden and disrupting the clinical workflow. This automated data exchange facilitates faster and more efficient disease tracking, case management, and contact tracing. Electronic case reporting provides more timely and complete data than manual reporting, including data on demographics, comorbidities, immunizations, medications, occupation, and other treatments.

Recent efforts by the CDC have sought to significantly improve the effectiveness of electronic case reporting through eCR Now, a strategic initiative that allows for rapid adoption and implementation of electronic case reporting for COVID–19 (*https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html*). As part of this initiative, CDC and its partners have developed an eCR Now FHIR® application (app) to establish electronic case reporting capability in EHR systems. EHR vendors can also implement the eCR functionality within their products to accomplish this reporting. The initiative also supports an electronic case reporting infrastructure that is helping to advance interoperability. This infrastructure supports the transmission of electronic case reports to a shared service platform, and not directly to a PHA, which means that any health care provider that has established an electronic case reporting connection also has a connection with every state PHA, many large local health departments, and some territories. This promotes nationwide interoperability and increases the availability of data for patients who may be traveling or spending time away from their home state. For example, if a patient is a resident of one state but seeks care in another state, this infrastructure will automatically route the case report to both states that would have jurisdiction over this report. This increases inter-jurisdictional reporting, allowing for more seamless case investigation at the national level. The interoperable infrastructure and the use of a standard data format also reduces the variability of case report forms across conditions and jurisdictions, streamlining reporting forms for EHR vendors and health care providers.

As a result of the CDC effort to scale up eCR Now for COVID–19, all 50 states, the District of Columbia, Puerto Rico and 12 large local jurisdictions have connected to the shared services platform and are currently receiving electronic case reports, with more than 8,800 healthcare facilities on board and 8.6 million reports for COVID–19

[223] *https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/2019-data.html.*

[224] CSTE State Reportable Condition Assessment page: *https://www.cste.org/page/SRCA.*

received by PHAs as of June 28, 2021.[225] The eCR infrastructure is designed to rapidly scale for PHEs, such as COVID–19, and it is enabled to currently support data transmission for 99 reportable and notifiable conditions. While these are significant advancements, the piecemeal approach of encouraging adoption of these tools by individual health care providers has not been an effective or efficient means to quickly scale this effort nationally as has been needed for the COVID–19 PHE response.

We believe the uneven adoption of electronic case reporting creates a public health vulnerability. We are proposing to make the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Promoting Interoperability performance category beginning with the performance period in CY 2022. For more information about the Electronic Case Reporting measure, we refer readers to the preamble discussion in prior rulemaking at 81 FR 77229. We believe making this a required measure would accelerate development of electronic case reporting capabilities in EHR systems, reduce health care administrative burden of complying with state-mandated disease reporting requirements, provide regulatory clarity for EHR vendors, and improve the timeliness, completeness, and utility of case report data for PHAs. We believe that requiring the Electronic Case Reporting measure would be feasible and beneficial for MIPS eligible clinicians. This change would encourage EHR vendors to make electronic case reporting available to their customers, which would make adoption of this capability relatively straightforward for MIPS eligible clinicians. To meet the CEHRT definition when reporting on this measure, in our EHR Incentive Program Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62870 through 62885) we established that health care providers are required to use a health IT module certified to the ''Transmission to public health agencies—electronic case reporting'' certification criterion at 45 CFR 170.315(f)(5) that relates to how the health IT uses structured data within an EHR to trigger or indicate the generation of an electronic initial case report.[226] They may then transmit the report in the manner specified by the case reporting requirements of the entity to which they are transmitting a report.

We believe that requiring the Electronic Case Reporting measure would not only provide certainty to EHR vendors and facilitate an organized and industry-wide rollout of electronic case reporting capabilities, but would also help health care providers reduce their public health reporting burden.

We are not proposing any changes to the description of the Electronic Case Reporting measure and the exclusions that we established in the CY 2019 PFS final rule at 83 FR 59815 through 59817 will remain available.

(cc) Proposed Scoring of the Public Health and Clinical Data Exchange Objective

We are proposing that beginning with the performance period in CY 2022, a MIPS eligible clinician would receive 10 points for the Public Health and Clinical Data Exchange objective if they report a ''yes'' response for each of the following required measures: Immunization Registry Reporting; and Electronic Case Reporting. In the event that a MIPS eligible clinician is able to claim an exclusion for one or more of these required measures, we are proposing they would receive 10 points for the objective if they report a ''yes'' response for one measure and claim an applicable exclusion for which they qualify for the remaining measure. If the MIPS eligible clinician fails to report on any one of the two measures required for this objective or reports a ''no'' response for one or more of these measures, we are proposing that the MIPS eligible clinician would receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Promoting Interoperability performance category. If an MIPS eligible clinician claims applicable exclusions for which they qualify for both required measures, we propose to redistribute the points associated with the objective to the Provider to Patient Exchange objective.

We are proposing to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures, and to make them optional and available for bonus points beginning with the performance period in CY 2022. For more information about these measures, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77229) and the EHR Incentive Program Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62818 through 62825). We are proposing a MIPS eligible clinician may earn 5 bonus points if they report a ''yes'' response for either the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure. Reporting on more than one of these optional measures would not yield additional bonus points.

In connection with our proposal to make these measures optional, we are proposing to remove the three exclusions that we established in the CY 2019 PFS final rule at 83 FR 59815 through 59817 for the Public Health Registry Reporting measure, Clinical Data Registry Reporting measure, and the Syndromic Surveillance Reporting measure.

We are seeking comment on these proposals.

(d) SAFER Guides

(i) Background

ONC developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated them in 2016. This series of nine user guides support the ability of health care providers to address EHR safety.[227] Collectively, the SAFER Guides help health care organizations at all levels, from small practices to multi-system chains and tertiary care facilities, to conduct self-assessments to optimize the safety and safe use of EHRs in the three areas listed in Table 43. The SAFER Guides are intended to be utilized by EHR users, developers, patient safety organizations, and those who are concerned with optimizing the safe use of health IT. Completing a self-assessment using the SAFER Guides is one of the first steps MIPS eligible clinicians can take to support a ''culture of safety'' within their organization, and ensure they are responsible operators of technology tools, including certified health IT products, which they utilize in the delivery of care. The SAFER Guides are based on the best evidence available at the time of publication, which included a literature review, expert opinion, and field-testing at a wide range of health care organizations, from small ambulatory care practices to large health systems.

In the case of system disruption, failure, natural disaster, the SAFER Guides provide recommended safety practices during planned or unplanned EHR unavailability, where end users are unable to access all or part of their EHR. Also included are back-up procedures to

[225] Healthcare Facilities in Production for COVID–19 Electronic Case Reporting | CDC.

[226] For more information about this certification criterion, please see the Certification Companion Guide at *https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting.*

[227] *https://www.healthit.gov/topic/safety/safer-guides.*

prevent the potential loss of clinical and administrative data, and how to utilize paper charting during such downtime. We believe that conducting an annual self-assessment starting with the High Priority Practices Guide would support consistent safety practices for all EHR users.

The High Priority Practices SAFER Guide identifies ''high risk'' and ''high priority'' recommended safety practices, intended to optimize the safety and safe use of EHRs.[228] This guide broadly discusses EHR safety concerns that are described in greater detail in the subsequent 8 SAFER Guides. The High Priority Practices Guide is considered the first to be completed of the 9 SAFER Guides.

TABLE 43: The SAFER Guides

Foundational Guides	- High Priority Practices - Organizational Responsibilities
Infrastructure Guides	- Contingency Planning - System Configuration - System Interfaces
Clinical Process Guides	- Patient Identification - Computerized Provider Order Entry with Decision Support - Test Results Reporting with Follow-Up - Clinician Communication

(ii) Proposed New SAFER Guides Measure

We are proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective, beginning with the CY 2022 performance period/2024 MIPS payment year. For this measure, we are proposing that a MIPS eligible clinician must attest to having conducted an annual self-assessment using the High Priority Practices Guide (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the performance period occurs, with one ''yes/no'' attestation statement accounting for the complete self-assessment using the guide. We propose that this measure would be required, but it would not be scored, and that reporting ''yes'' or ''no'' would not affect the total number of points earned for the Promoting Interoperability performance category. We believe this measure would further enable the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, as described in section 1848(o)(2)(A)(ii) of the Act. We are also proposing to add corresponding regulatory text for this measure at § 414.1375(b)(2)(ii)(C).

In order to complete a ''self-assessment'' using the High Priority Practices Guide, we would expect that each MIPS eligible clinician would complete a review and mark the associated checkboxes (fully, partially, or not implemented) of recommended practices included at the beginning of the Guide. Detailed worksheets with the rationales for, and examples of how, to implement each recommended practice follows the checklist section of the Guide. These worksheets also include likely sources of information the practice can turn to in order to complete their assessment of a recommended practice, as well as fillable note fields to record follow-up actions.

We understand that every organization faces unique circumstances, and will implement a particular practice differently. As a result, some of the specific examples in the SAFER Guides for recommended practices may not be applicable to every organization. We note that a ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice described in a particular SAFER guide, nor will an organization be scored on how many of the practices the organization has fully implemented. Rather, the intent of this proposed requirement is for MIPS eligible clinicians to regularly assess their progress and status on important facets of patient safety.

The recommended practices in the SAFER Guides are intended to be useful for all EHR users. However, we recognize that the individuals responsible for the proposed annual assessment may vary across organizations. An optimal team for completing an annual review of the SAFER Guides might include clinicians (including physicians, nurses, pharmacists, and allied health staff), and the technical staff responsible for implementing and maintaining a practice's EHR as well as data connections with external partners (for example, an HIE). Regarding the frequency of completing the self-assessment for the High Priority Practices Guide, we are proposing that a MIPS eligible clinician must attest to completing their assessment using the High Priority Practices Guide on an annual basis, following an initial completion of the assessment (some clinicians may have already completed an assessment using the SAFER Guides prior to implementation of this requirement, if finalized). We would expect MIPS eligible clinicians to revisit this assessment to determine whether any changes have occurred for their organization. We believe that requiring MIPS eligible clinicians to periodically review this self-assessment as proposed would support a stronger culture of change management within organizations, and would assist organizations in actively understanding and addressing potential safety vulnerabilities, which may significantly impact an organization's safety posture. We recognize that organizations may be at different stages in their progress towards assessing patient safety vulnerabilities, and that MIPS eligible clinicians vary in the resources that they could devote to an annual review of the High Priority Practices Guide. Gathering this information may be time consuming for some, and others may not have the expertise available on staff to complete all of the requirements. For MIPS eligible clinicians with less experience in these areas, we note that there are a number of resources available, which

[228] *https://www.healthit.gov/sites/default/files/safer/guides/safer_high_priority_practices.pdf.*

may be able to assist with completing a self-assessment.

We are inviting public comment on these proposals.

(e) Incrementation of the Numerator and Denominator for Promoting Interoperability Performance Category Measures

In the CY 2019 PFS final rule (83 FR 59799), we summarized a comment we received in response to proposals we had made in the CY 2019 PFS proposed rule concerning the measures for the Promoting Interoperability performance category beginning with the performance period in 2019. The commenter indicated that for some measures, MIPS eligible clinicians and group practices should be able to get credit for actions that are taken outside of the 90-day performance period. We responded to the comment by stating that since the inception of the Quality Payment Program, we have limited the ability to increment the numerator and denominator of measures to actions occurring during the performance period chosen, with the exception of the Security Risk Analysis measure, for which the relevant actions may occur any time during the calendar year. We now understand that our response to this comment may have caused confusion, and we wish to clarify our response. Instead of referring to the inception of the Quality Payment Program, we should have stated that the measures we proposed beginning with the performance period in 2019 would limit the ability to increment the numerator and denominator to actions occurring during the performance period chosen, with the exception of the Security Risk Analysis measure, for which the relevant actions may occur any time during the calendar year. We note an additional exception would be the SAFER Guides measure (as proposed in section IV.A.3.d.(4)(d) in this proposed rule) because the relevant actions may also occur at any time during the calendar year.

(f) Changes to the Scoring Methodology for the 2022 Performance Period

For ease of reference, Table 44 lists the objectives and measures for the Promoting Interoperability performance category for the performance period in CY 2022 as revised to reflect the proposals made in this proposed rule. Table 45 lists the 2015 Edition certification criteria required to meet the objectives and measures.

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TABLE 44: Objectives and Measures for the Promoting Interoperability Performance Category in 2022

Objective	Measure	Numerator	Denominator	Exclusion
e-Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing: At least one permissible prescription written by the MIPS eligible clinician is queried for a drug formulary and transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription in order to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
e-Prescribing: Generate and transmit permissible prescriptions electronically.	Query of PDMP (bonus): For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the MIPS eligible clinician that transitions or refers their patient to another setting of care or health care provider (1) creates a summary of care using CEHRT; and (2) electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.

Objective	Measure	Numerator	Denominator	Exclusion
summary of care information from other health care providers into their EHR using the functions of CEHRT.				
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT.	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	Any MIPS eligible clinician who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a	HIE Bi-Directional Exchange	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
new patient, and reconciles summary of care information from other health care providers into their EHR using the functions of CEHRT.				
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	Number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download, and transmit to a third party and to access using an application of their choice that is configured meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a	Immunization Registry Reporting: The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2.operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to

Objective	Measure	Numerator	Denominator	Exclusion
meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	information system (IIS).			meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Electronic Case Reporting: The MIPS eligible clinician is in active engagement with a public health agency to electronically submit case reporting of reportable conditions.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	The MIPS eligible clinician: 1.Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the performance period; OR 2.operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Public Health Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit data to public health registries.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with	Clinical Data Registry Reporting: (bonus) The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

Objective	Measure	Numerator	Denominator	Exclusion
a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.				
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Syndromic Surveillance Reporting: (bonus) The MIPS eligible clinician is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Protect Patient Health Information	Security Risk Assessment	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none
Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	High Priority Practices Guide	N/A (measure is Yes/No)	N/A (measure is Yes/No)	none

TABLE 45: Promoting Interoperability Performance Category Objectives and Measures in 2022, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange	HIE Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include, but are not limited to, technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access – patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access – all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(4) Transmission to public health agencies — transmission to cancer registries § 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
Protect Patient Health Information	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion.
Protect Patient Health Information	Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)	None

Table 46 reflects the scoring methodology for the Promoting Interoperability performance category for the performance period in CY 2022, if the proposed changes discussed earlier in this section are adopted as final, including the continuation of the optional Query of PDMP measure worth 10 bonus points for CY 2022, changes to the Provide Patients Electronic Access to Their Health Information Measure under the Provider to Patient Exchange objective, the adoption of a SAFER Guides measure, and modified requirements for the Public Health and Clinical Data Exchange objective.

TABLE 46: Scoring Methodology for the Performance Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange -OR-	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
Health Information Exchange (alternative)	Health Information Exchange Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information*	40 points
Public Health and Clinical Data Exchange	Report the following 2 measures:* • Immunization Registry Reporting • Electronic Case Reporting	10 Points
	• Public Health Registry Reporting OR • Clinical Data Registry Reporting OR • Syndromic Surveillance Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure and the SAFER Guides measure are required, but will not be scored.
* Signifies a proposal made in this CY 2022 PFS proposed rule.

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We also refer readers to section IV.A.3.e. of this proposed rule, where we are proposing changes to the regulatory text for scoring the Promoting Interoperability performance category at § 414.1380(b)(4)(ii).

(g) Actions To Limit or Restrict the Compatibility or Interoperability of CEHRT

(i) Background

Section 106(b)(2) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) includes the heading ''Preventing Blocking The Sharing Of Information.'' Section 106(b)(2)(A) amended section 1848(o)(2)(A)(ii) of the Act to require that, to be a meaningful EHR user, a clinician demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the clinician has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology. To implement these provisions, we established and codified at § 414.1375(b)(3)(ii) attestation requirements for the Promoting Interoperability performance category to support the prevention of information blocking, which consist of three statements containing specific representations about a MIPS eligible clinician's implementation and use of CEHRT. For further discussion on these requirements, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035). The attestation statements finalized for MIPS eligible clinicians at § 414.1375(b)(3)(ii) are:

- *Statement A:* Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.
- *Statement B:* Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
- *Statement C:* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

Section 4004 of the 21st Century Cures Act added section 3022 to the Public Health Service Act (PHSA) (the ''PHSA information blocking provision,''), which describes practices by health care providers, health IT developers, and HIEs and networks, that constitute information blocking, and provides for civil monetary penalties and other disincentives for those who engage in information blocking.

In the ONC 21st Century Cures Act final rule published in the May 1, 2020 **Federal Register**, ONC finalized a definition of information blocking and identified reasonable and necessary activities (''exceptions'') that do not constitute information blocking (85 FR 25642). For health care providers (as defined in 42 U.S.C. 300jj), information blocking means a practice that, except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (45 CFR 171.103).

The 21st Century Cures Act provides for civil monetary penalties for any individual or entity that is a developer, network, or exchange that has committed information blocking (see section 3022(b)(2)(A) of the PHSA). Regarding health care providers, the 21st Century Cures Act provides that ''Any [health care provider] determined by the [HHS] Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable

federal law, as the Secretary sets forth through notice and comment rulemaking'' (section 3022(b)(2)(B) of the PHSA).

(ii) Proposed Changes to the Attestation Statements

Although there could be some degree of overlap between conduct described in the attestation statements under § 414.1375(b)(3)(ii) and conduct that could be considered information blocking under section 3022 of the PHSA and ONC's implementing regulations at 45 CFR 171.103, it is important to note these are separate and distinct authorities. For instance, the ONC 21st Century Cures Act final rule finalized a definition for what constitutes information blocking, and exceptions to information blocking that are not reflected in the previously finalized attestation statements under § 414.1375(b)(3)(ii). While we previously stated in the 2017 QPP final rule that these attestations statements did not impose ''unnecessary or unreasonable requirements'' on health care providers (81 FR 77029), after careful review of these attestation statements in light of the information blocking regulations at 45 CFR part 171, we believe that statements B and C are no longer necessary. Thus, beginning with the performance period in CY 2022, we are proposing to no longer require statements B and C. We believe that the similarities between practices described under statements B and C, and the practices that could constitute information blocking under section 3022 of the PHSA and ONC's implementing regulations will create confusion for stakeholders. To this point, the practices that could constitute information blocking under 45 CFR part 171 are much broader than those described in the attestation statements. We discuss specific instances of potential confusion below.

Statement B requires attestation to a series of statements regarding the use of certified technology and a designated manner for implementing certified technology. For instance, attestations to the implementation of technology compliant with the standards for certified health IT at 45 CFR part 170, and use of functionality to support health information exchange with other health care providers. However, as noted above, the definition of information blocking finalized in the ONC 21st Century Cures Act final rule is not specific to, nor limited to the use of certified technology, which is compliant with certain standards or the use of certain functionality. Under the ONC 21st Century Cures Act final rule, a health care provider may still be determined to have engaged in practices likely to interfere with access, exchange, or use of electronic health information (information blocking) regardless of whether they are using certified technology.

Regarding statement C, we stated in the 2017 QPP final rule that ''technical, legal, and other practical constraints may prevent a health care provider from responding to some requests to access, exchange, or use electronic health information in a health care provider's certified EHR technology'' (81 FR 77033). Subsequently, in the ONC 21st Century Cures Act final rule, ONC established a set of reasonable and necessary activities that are not considered information blocking when responding to a request for EHI. The reasonable and necessary activities established under the ONC 21st Century Cures Act final rule now provide more specific direction to health care providers when responding to a request for EHI than the general ''technical, legal, and other practical constraints,'' which we described in the CY 2017 QPP final rule. Accordingly, we believe that continuing to require statement C may introduce confusion for those health care providers who are obligated to comply with the regulations finalized in the ONC 21st Century Cures Act final rule when responding to a request for EHI.

In order to distinguish the attestation required by section 106(b)(2)(A) of MACRA from information blocking under section 3022 of the PHSA, we are proposing to modify the headings of §§ 414.1375(b)(3) and (b)(3)(ii), add § 414.1375(b)(3)(iii), and modify the definition of ''meaningful EHR user for MIPS'' under § 414.1305 to specify that the clinician does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, which reflects the language used in section 106(b)(2)(A) of MACRA. In addition, as discussed, we are proposing to no longer require attestation statements B and C beginning with the performance period in CY 2022, and we are proposing corresponding regulatory text amendments at § 414.1375(b)(3)(ii) and (iii). We made a similar proposal for the Medicare Promoting Interoperability Program in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25639 through 25641).

We invite public comment on our proposal.

(h) Additional Considerations

(i) Reweighting the Promoting Interoperability Performance Category for MIPS Eligible Clinicians in Small Practices

We previously established under § 414.1380(c)(2)(i)(C)(9) a significant hardship exception for MIPS eligible clinicians in small practices as defined in § 414.1305. In the CY 2018 Quality Payment Program final rule (82 FR 53682 through 53683), we established that we will reweight the Promoting Interoperability performance category to zero percent of the MIPS final score for MIPS eligible clinicians who qualify for this hardship exception. We established that a MIPS eligible clinician seeking to qualify for this exception must submit an application to us demonstrating that there are overwhelming barriers that prevent them from complying with the requirements for the Promoting Interoperability performance category, and that the exception is subject to annual renewal. In the CY 2018 Quality Payment Program final rule (82 FR 53579 through 53581), we also established that we will determine the size of small practices by utilizing claims data. This policy was further modified in the CY 2019 PFS final rule (83 FR 59727 through 59730) so that beginning with the 2021 MIPS payment year, a small practice is a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period.

In the CY 2018 Quality Payment Program proposed rule (82 FR 30076), we stated that we believed that special consideration should be available for MIPS eligible clinicians in small practices based on concerns previously identified by commenters, including small practices not being able to afford the upfront investments (including investments in EHR technology), and small practices not adopting EHRs due to the administrative and financial burden. Although some commenters requested that we automatically apply the proposed hardship exception to clinicians in small practices, at the time we disagreed and stated that we believed that many small practices will be able to successfully report for the Promoting Interoperability performance category (82 FR 53683).

We have been monitoring the submission of data for the Promoting Interoperability performance category by small practices and individual clinicians who are part of a small practice, and the numbers remain low despite the no-cost technical assistance we offered small practices through the Small, Underserved, and Rural Support Initiative. Data from CY 2019 revealed

that of the 49,278 clinicians in small practices who were scored as an individual for MIPS, 84 percent of them did not submit Promoting Interoperability performance category data and did not apply for a small practice hardship exception application even though they may have qualified for the exception. Among clinicians who did not qualify for Promoting Interoperability performance category reweighting, only 29 percent of small practices compared to 61 percent of practices with more than 15 clinicians billing under the practice's TIN submitted data for the Promoting Interoperability performance category. Although we had expected many small practices would be able to successfully report data for the Promoting Interoperability performance category, we are concerned to see such low numbers of them either reporting data or applying for the small practice hardship exception, as such inaction would result in a score of zero for this performance category.

We want to support small practices and help them successfully participate in MIPS. As our analysis of the data suggests that successfully participating in the Promoting Interoperability performance category may be particularly challenging for small practices, we are proposing a modification of our policy. Beginning with the CY 2022 performance period/CY 2024 MIPS payment year, we are proposing to no longer require an application for clinicians and small practices seeking to qualify for the small practice hardship exception and reweighting. We are proposing instead to assign a weight of zero percent to the Promoting Interoperability performance category and redistribute its weight to another performance category or categories (as discussed further in section IV.A.3.e. of this proposed rule) in the event no data is submitted for any of the measures for the Promoting Interoperability performance category by or on behalf of a MIPS eligible clinician in a small practice. We are proposing that if data is submitted for a MIPS eligible clinician in a small practice, they would be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians, and the performance category would be given the weight prescribed by section 1848(q)(5)(E) of the Act. We are proposing the small practice significant hardship exception still would be subject to annual renewal, and we would verify whether a practice meets the definition of a small practice under § 414.1305 on an annual basis. We are proposing corresponding revisions to § 414.1380(c)(2)(i)(C)(9).

While we are proposing this policy at this time, it is not our intention that this policy be in place for the long term, but rather only for a few years, as we would like to increase participation of small practices in the Promoting Interoperability performance category. We would like to facilitate small practices successfully reporting data for the Promoting Interoperability performance category and are therefore seeking comment on potential options to increase small practice participation in the future. We are also seeking comment on why small practices that have not successfully reported for the Promoting Interoperability performance category not applied for the small practice hardship exception. Are practices choosing not to apply due to the requirement that they must have overwhelming barriers that prevent them from complying with the requirements for the Promoting Interoperability performance category? Is there confusion about what would be considered an overwhelming barrier? Are they aware that the small practice hardship exception is available? We are also interested in hearing about barriers that exist that prevent the adoption of CEHRT and/or the ability to submit Promoting Interoperability performance category measures. Are small practices wanting to adopt CEHRT but lack the resources?

Have practices previously adopted CEHRT but face barriers in upgrading to the edition of certified health IT currently required to meet the CEHRT definition for the Quality Payment Program? Alternatively, have these practices consciously chosen not to adopt CEHRT because of impending retirement or other factors? Are there other policies that we could pursue to remove barriers to or incentivize participation in the Promoting Interoperability performance category by small practices?

We are proposing that in the case of an APM Entity that also meets the definition of a small practice, we would continue applying the Promoting Interoperability performance category reporting and exception requirements at the group level, as described at § 414.1317. However, if the APM Entity is composed of a single TIN which itself meets the definition of a small practice, all TINs within the APM Entity (that is, the single TIN) would be eligible for this exception, and therefore the Promoting Interoperability performance category would be reweighted for the APM Entity and the performance category reweighting described above would be applied.

We are seeking comments on this proposal.

(ii) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

We established a policy at § 414.1380(c)(2)(i)(A)(*5*) for the performance periods in 2017 through 2021 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. Although we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For the 2017 performance period, approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. For the 2018 performance period, we reported that of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually, approximately 34 percent submitted data for the Promoting Interoperability performance category. However, after further review and the refinement of our analytics it was revealed that the percentage was not 34 percent but was 24 percent of MIPS eligible clinicians

who are NPs, PAs, CRNAs, or CNSs that submitted data individually for the Promoting Interoperability performance category. For the 2019 performance period, of the MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs and submitted data individually, approximately 30 percent submitted data individually for the Promoting Interoperability performance category, a modest increase from 2018. We continued our reweighting policy in 2020 although we do not yet have data from submissions for the CY 2020 performance period and do not expect it to be available prior to the release of this proposed rule.

We believe that having these clinician types using CEHRT and submitting data for the Promoting Interoperability performance category is important for increased interoperability and data exchange. We are exploring the possibility that these clinician types are able to submit data but are choosing not due to our current reweighting policies. In the future we may use other factors besides the submission data to determine whether to continue to reweight the Promoting Interoperability performance category for these clinicians. We are requesting comments as to whether these clinician types are using CEHRT and are able to submit data on the measures for the Promoting Interoperability performance category.

While we are encouraged by the increasing numbers of NPs, PAs, CRNAs, and CNSs submitting data for the Promoting Interoperability performance category, we believe that the low numbers warrant the continued reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2022. Thus, we are proposing to continue the existing policy for the 2022 performance period/2024 MIPS payment year and are proposing to revise § 414.1380(c)(2)(i)(A)(*5*), which is being redesignated as § 414.1380(c)(2)(i)(A)(*4*)(*ii*), to reflect the proposal.

We request comments on this proposal.

(iii) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2020 PFS final rule (84 FR 63003 through 63004), we adopted a policy at § 414.1380(c)(2)(i)(A)(*4*) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs to other types of MIPS eligible clinicians who are NPPs (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2020. We stated that because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category. We extended this policy for the performance period in 2021 (85 FR 84895). As these clinicians were first eligible to participate in 2020, we do not have data to rely on to modify our current policy and do not anticipate it being available prior to the release of this proposed rule. Therefore, we are proposing to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the 2022 performance period/2024 MIPS payment year. We propose to revise § 414.1380(c)(2)(i)(A)(*4*), which is being redesignated as § 414.1380(c)(2)(i)(A)(*4*)(*i*), to reflect this proposal.

We request comments on this proposal.

(iv) Clinical Social Workers and Certified Nurse-Midwives

In section IV.A.3.a. of this proposed rule, we are proposing to add clinical social workers and certified nurse-midwives to the definition of a MIPS eligible clinician. These clinician types were not eligible to participate in the Medicare Promoting Interoperability Program to earn incentive payments for meaningful use of CEHRT or receive reduced Medicare payments for failing to meaningfully use CEHRT. Clinical social workers were not eligible for Medicaid EHR incentive payments and thus may lack experience with the adoption or use of CEHRT. Certified nurse-midwives were eligible for the Medicaid EHR incentive payments, and the majority did earn incentives. For the CY 2022 performance period/CY 2024 MIPS payment year, we are proposing to apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to clinical social workers as we believe that there may not be sufficient Promoting Interoperability performance category measures that are applicable and available to clinical social workers. We would assign a weight of zero only in the event that a clinical social worker does not submit data for any of the measures specified for the Promoting Interoperability performance category. We are proposing to add § 414.1380(c)(2)(i)(A)(*4*)(*iii*) to reflect this proposal for clinical social workers.

We believe there are sufficient measures applicable and available to certified nurse-midwives under the Promoting Interoperability performance category because of their experience with the Medicaid Promoting Interoperability Program. Many of them have adopted CEHRT and earned a Medicaid incentive payment, and the measures for the Medicaid Promoting Interoperability Program generally are the same or slightly modified versions of the Promoting Interoperability performance category measures. Thus, we are not proposing to apply the same Promoting Interoperability reweighting policy we adopted previously for NPs, PAs, CNSs, CRNAs, and other types of MIPS eligible clinicians to certified nurse-midwives. However, we are requesting comment on whether there are in fact sufficient measures applicable and available to certified nurse-midwives under the Promoting Interoperability performance category, and whether barriers exist that prevent certified nurse-midwives from complying with the requirements of the Promoting Interoperability performance category and may warrant reweighting. Like other types of MIPS eligible clinicians, a certified nurse-midwife may be able to qualify for a significant hardship exception from and reweighting of the Promoting Interoperability performance category under the existing policies at § 414.1380(c)(2)(i)(C), depending on their circumstances.

We request comments on this proposal.

(i) Technical Corrections to the Regulations

In the CY 2019 PFS final rule (83 FR 59798 through 59817), we adopted objectives and measures for the Promoting Interoperability performance category that would apply beginning with the performance period in 2019. The requirement for MIPS eligible clinicians to report on these objectives and measures can be found under § 414.1375(b)(2). In the CY 2021 PFS rulemaking, we inadvertently neglected to update this provision of the regulation text, although our intention was a continuation of the policy we established for the 2021 and 2022 MIPS

payment years. We are proposing a technical correction to § 414.1375(b)(2)(ii) to specify that the reporting requirements apply beginning with the 2021 MIPS payment year. We request comments on this proposal.

(j) Requests for Information

(i) Request for Information on Additional Objectives Adopting FHIR®-Based API Standards

Fast Healthcare Interoperability Resources (FHIR®) (*http://hl7.org/fhir*) is a free and open-source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health IT, it allows systems to communicate and information to be shared seamlessly with a lower burden on stakeholders. Through the HL7® FHIR® standard, cost and burden for health care providers and patients are reduced since it simplifies implementation without sacrificing information integrity, establishes fast, efficient, and flexible health data exchange as a stand-alone standard or combined with existing standards. Essentially, HL7®'s FHIR® standard framework provides an interoperable platform for a variety of health care data by defining a standard way to structure this information as 'resources' and allows the developer-friendly automated data-exchange to occur via APIs. The use of APIs utilizing the FHIR® standard has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. Given the progress of such emerging health IT innovation standards to promote interoperability at large, we see increased adoption of approaches utilizing the latest HL7® FHIR® standard as an opportunity to consider how these approaches can support other program goals.

In the CY 2021 PFS final rule, we finalized alignment of the CEHRT definition for the Promoting Interoperability programs with updates to 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule. As part of the ONC 21st Century Cures Act final rule, ONC finalized a new certification criterion ''Standardized API for patient and population services'' at 45 CFR 170.315(g)(10) which supports the availability in certified health IT of an API using the FHIR® Release 4 standard and other implementation specifications. We noted that technology certified to this criterion will be used to support the API requirements in the Provide Patients Access to their Health Information objective. Regarding the bi-directional HIE measure finalized for MIPS eligible clinicians in the CY 2021 PFS final rule (85 FR 84888 through 84893), we also noted that the standards-based API criterion at 45 CFR 170.315(g)(10) could be used to support connections to an HIE in order to complete the measure's actions.

We are seeking comments on our intention to align additional Promoting Interoperability performance category objectives with approaches utilizing HL7® FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. Throughout this ongoing developmental process, we are partnering with ONC and continuing to strengthen collaboration on the implementation of the 21st Century Cures Act final rule.

We are interested in public comments on how these two program objectives could be furthered through the use of FHIR®-based API solutions. Specifically, we are interested in the following questions:

- To what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective? What revisions to the measures under the HIE objective should CMS explore to facilitate use of standards-based APIs in health IT modules certified under the 2015 Edition Cures Update?
- How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures? What are promising FHIR®-based approaches to public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability performance category and the ONC Health IT Certification Program?
- To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting? What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?
- What potential policy and program changes in CMS and other HHS programs could reduce health care provider and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?

(ii) Request for Information on a Patient Access Outcomes Measures

The evolution of EHRs has created a greater and more seamless flow of information within a digital health care infrastructure which allows for comprehensive records to be made available wherever and whenever they are needed in the clinical setting. These advances have led to: (1) Improved patient care; (2) increased patient participation; (3) improved care coordination; (4) greater practice efficiencies and cost savings; and (5) improved diagnostics and patient outcomes.[229] Much research effort has been dedicated to looking at the implementation of health IT in practice settings with its wide array of potential benefits, but equally important to the success of this EHR-advancement is better understanding the patient's role as an active end-user as well.

Several large, nationally representative surveys have been completed annually in order to collect and evaluate the public's access and use of health information. One of these endeavors operated by the National Cancer Institute (with support from ONC) is The Health Information National Trends Survey (HINTS) [230] that produces a plethora of key utilization data specifically pertaining to consumers' access and use of their online medical records via patient portals. The HINTS results point to an overall year-over-year rise in the number of Americans who are not only accessing their medical records online (from 51 percent in 2018 to 58 percent in 2019) [231] but are increasingly doing so to perform meaningful actions such as to view lab test results, transmit their data to a third-party, and to securely message their health care provider. While sources like the HINTS survey are revealing preferential trends, habits, and other key utilization points, the data also show some strong barriers associated with patients accessing CEHRT and continue to stress the need for further work in understanding these users' access outcomes.

We believe a strong partnership between EHR vendors, health care providers, and beneficiary users' outcomes is critical to improving the future of health care and furthering interoperability. Therefore, we are seeking comments surrounding changes

[229] *https://www.healthit.gov/topic/health-it-basics/benefits-ehrs.*

[230] *https://hints.cancer.gov/.*

[231] Patel, V. Johnson, C. (2020). The Current State of Patients' Access and Use of their Electronic Health Information [PowerPoint presentation]. The Office of the National Coordinator for Health Information Technology Annual Meeting.

to the Promoting Interoperability performance category and related efforts which could better target patient access outcomes related to use of patient portals or third-party application(s). This request for information is an opportunity to garner general interest, solicit stakeholder feedback on how to best evaluate issues of patient behavior, and to explore additional key outcome variables to capture for measurement.

Specifically, we are looking for feedback on the following questions:

- What do stakeholders believe would be useful ways to measure patients' access to their electronic health information using health IT methods such as patient portals and/or third-party applications? What actionable figures related to users' medical record behavior, including but not limited to, the frequency of logins, number of messages sent, or lab results viewed could be captured?
- How effectively is the Promoting Interoperability performance category currently measuring the use of health IT-enabled processes to improve patient outcomes? What measures in the current performance category are most relevant to patient outcomes?
- Should we consider requiring health care providers to maintain a record of third-party applications which patients have used to access their patient health information through APIs incorporated within certified technology so that this information could be used to assess patient usage of these applications?
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability performance category) that can increase patient utilization of tools to access their health information? How do these technologies and features support improved access or usability within EHR systems and other applications (for instance, alternate authentication technologies that can simplify consumer logon)? How could CMS reward health care providers for higher adoption rates and use of these available technologies?
- What are key administrative processes that could benefit from more efficient electronic workflows? How could CMS measure and reward participating MIPS eligible clinicians for either greater uptake of patient portal access or subsequent health outcomes?

(iii) Request for Information on Clinical Notes

OpenNotes is an international movement aimed to spread and study the effects of transparent communication among patients, families, and clinicians.[232] With more than 50 million patients in the U.S. and Canada having gained access to their clinical notes, the push for patient engagement and transparent communication continues to grow.[233] Alongside this movement, ''Clinical notes'' have been regarded as highly desirable data necessary for the interoperable exchange of health information and patient access. Comprised of structured and unstructured data, clinical notes may include the assessment, diagnosis, plan of care and evaluation of plan, patient teaching, and other relevant data (85 FR 25674).

While the ability to share clinical notes has been previously supported for certified health IT in different ways, ONC took additional steps to ensure this important patient information is available as part of the recent ONC 21st Century Cures Act final rule (85 FR 25674 through 25677). In the rule, ONC finalized eight types of ''clinical notes'' required under the USCDI version 1: (1) Discharge Summary Note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedure Note.[234]

As previously discussed in the CY 2021 PFS final rule (85 FR 84825), we finalized to align the CEHRT definition under the Promoting Interoperability performance category with the timelines established under the ONC 21st Century Cures Act final rule for implementation of the 2015 Edition Cures Update. This alignment includes updates to several certification criteria to refer to the USCDI and the expanded support for clinical notes specified in the USCDI version 1 standard. New and updated certification criteria incorporating the USCDI, include the ''view, download, and transmit'' criterion at 45 CFR 170.315(e)(1), and the ''Standardized API for patient and population services'' criterion at 45 CFR 170.315(g)(10). Once EHR developers and MIPS eligible clinicians have completed implementation of these updates, certified health IT required for participation in the Promoting Interoperability performance category will support availability of clinical notes as part of the data set made available to patients under the Provide Patients Access to their Health Information measure. According to the policy finalized in the CY 2021 PFS final rule, MIPS eligible clinicians may begin using updated technology as soon as it is available from their vendors (effective upon the effective date of the CY 2021 PFS final rule), with updated technology being required for performance periods beginning in CY 2023.

Under this RFI, we are seeking stakeholder feedback on changes we can make that will better support the goals of the OpenNotes movement to ensure that clinical notes are widely available to patients. Given the implementation of updates to certified technology described above that support the Provide Patients Access to their Health Information measure, are there additional changes to this measure, or other program guidance, which could further facilitate ensuring clinical notes are available to patients consistent with the goals of the OpenNotes movement? We are also seeking feedback on the development of a required and independently scored measure for the Promoting Interoperability performance category to allocate points for the use of ''clinical note'' types supported by certified health IT. Finally, we are seeking comment on the types of clinical notes that are commonly sought, but not easily accessible to patients. We included a similar RFI under the Medicare Promoting Interoperability Program in the FY 2022 IPPS/LTCH proposed rule (86 FR 25654).

(5) APM Entity Level Participation for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

In the CY 2021 PFS final rule (85 FR 84896), we finalized our policy to terminate the APM scoring standard effective January 1, 2021, and to retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the CY 2021 MIPS performance period. Therefore, we redesignated, in part, the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and titled that section ''APM Entity Groups.''

(b) APM Entity Level Reporting of Facility-Based Measures

In the CY 2021 PFS final rule (85 FR 84896), we finalized a policy to allow APM Entities to report to traditional MIPS using the same quality measures available to other groups, according to all applicable MIPS quality scoring policies. It has been brought to our attention that we did not make it clear

[232] *https://www.opennotes.org/about/*.

[233] *https://www.opennotes.org/history/*.

[234] Link to the Clinical Notes Argonaut Project *https://www.healthit.gov/isa/uscdi-data/clinical-notes#uscdi-v1*.

whether APM Entities may be eligible for facility-based scoring. We would like to clarify that because facility-based measures are not submitted, but rather collected by CMS using group-level participation scores used for the Hospital Value Based Purchasing Program, it would be impossible for CMS to calculate a score for a facility-based measure that represents the performance of an APM Entity. Therefore, facility-based scoring is not available to APM Entities under MIPS quality scoring rules, as described at § 414.1330. We note that participants in APM Entities that are eligible for facility based scoring at the individual or group level would still be eligible to receive these scores for purposes of individual or group MIPS scoring.

(c) APM Entity Performance Category Weights

In the CY 2021 PFS final rule (85 FR 84896), we finalized a policy to weight the cost performance category at zero percent of the final score for APM Entities in MIPS APMs. We codified the weight of the cost performance category at § 414.1317(b)(2), but we did not discuss in the CY 2021 PFS final rule how the weight that otherwise would have applied to the cost performance category will be redistributed among the other performance categories. For purposes of clarity, we propose to add to § 414.1317(b)(2) that the performance category reweighting scenarios under § 414.1380(c)(2) apply to an APM Entity.

Because APM Entities are participating in traditional MIPS and generally are being scored according to traditional MIPS scoring rules at § 414.1380 unless otherwise specified, the performance category reweighting scenarios under § 414.1380(c)(2) are applicable to APM Entities. Using the 2021 MIPS performance period/2023 MIPS payment year as an example, if the cost performance category is the only performance category weighted at zero percent for an APM Entity, the performance category weights would be as follows under § 414.1380(c)(2)(ii)(E): Quality 55 percent, cost zero percent, improvement activities 15 percent, and promoting interoperability 30 percent. If both cost and promoting interoperability are weighted at zero percent, then quality would be 85 percent and improvement activities would be 15 percent. For the remaining reweighting scenarios for the 2021 MIPS performance period/2023 MIPS payment year, we refer readers to Table 6 under § 414.1380(c)(2)(ii)(E). The reweighting scenarios applicable to APM Entities for the 2022 MIPS performance period/2024 MIPS payment year can be found in Table 7 under § 414.1380(c)(2)(ii)(F). We refer readers to section IV.A.3.e.(2)(a) of this proposed rule where we propose to apply the reweighting policy finalized for the 2022 MIPS performance period/2024 MIPS payment year at § 414.1380(c)(2)(ii)(F) to the 2025 MIPS payment year and each subsequent MIPS payment year. In the event we establish additional reweighting scenarios, they would also apply to APM Entities.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the CY 2022 performance period/2024 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. The scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. We are updating many of our scoring policies, focusing on removing transition policies. Specifically, we are proposing to—

- Change certain terminology related to scoring.
- Amend our scoring flexibility policy to include quality measures with omitted or deactivated codes in the finalized measure specifications.
- Implement benchmarking and topped out scoring policies that are responsive to potential low reporting rates for the CY 2020 performance period/2022 MIPS payment year due to the national PHE for COVID–19 and establishing a benchmark when measures are suppressed in the baseline period.
- Amend policies for scoring quality measures based on achievement and measures that do not meet case minimum or have a benchmark and introduce scoring policies for new measures.
- Amend the minimum case requirement policy.
- End the high priority and end to end reporting bonuses in the quality performance category.
- Continue improvement scoring in the quality performance category.
- Implement a scoring flexibility policy for changes that impact cost measures during the performance period.
- Revise certain provisions of the regulation text for the Promoting Interoperability performance category.

We are not proposing changes to scoring policies for the improvement activities performance category.

We have maintained our approach that MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, comprised of their performance category scores, and calculated according to the final score methodology. We refer readers to § 414.1380 for policies on scoring.

(b) Terminology Updates

We are proposing updates to § 414.1380 in an effort to more clearly and concisely capture previously established policies. These proposed updates are not intended to be substantive in nature, but rather to bring more clarity to the regulatory text. We are proposing to change the term ''performance category percent score'' to ''performance category score'' in § 414.1380(b)(1)(vi)(C) and (E) related to improvement scoring, § 414.1380(b)(1)(vii) related to scoring the quality performance category score, § 414.1380(b)(2)(iii) and (v) related to scoring the cost performance category, § 414.1380(c) and (c)(2)(ii)(A) on calculating the final score and final score reweighting, and § 414.1380(e)(6)(iv) and (v) related to facility-based scoring. Again, these changes are not intended to change the underlying policies reflected in the regulation text. Initially, the quality and cost performance categories used the term ''performance category percent score'' because those categories had improvement scoring and have a slightly different approach to calculation than the Promoting Interoperability and improvement activities performance category. However, the terms ''performance category percent score'' and ''performance category score'' have been used in the same way. For that reason, we are proposing to consolidate our language and use only the latter aforementioned term.

(c) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We refer readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913). We propose to amend policies

finalized in prior years to simplify scoring in MIPS as we transition to MVPs.

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period or Prior to Implementation

We refer readers to CY 2018, CY 2019, and CY 2021 Quality Payment Program final rules (82 FR 53714 through 53716, 83 FR 59845 through 59847, and 85 FR 84898 through 84901 respectively) and § 414.1380(b)(1)(vii)(A) for our previously establish scoring flexibilities policy.

In the CY 2018 Quality Payment Program Final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 coding changes during the performance period based only on the first 9 months of the 12-month performance period. We noted that we believe that 9 months of data is sufficient to assess performance when 12 months of data is not available. We finalized that we would publish a list of measures requiring 9 months of data on the CMS website by October 1st of the performance period if technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period) (82 FR 53716). We refer readers to § 414.1380(b)(1)(viii) for more on our policy for scoring flexibility for ICD–10 changes.

In the CY 2019 Quality Payment Program final rule (83 FR 59845 through 59847), we finalized policies beginning with the 2019 performance period/2021 MIPS payment year to reduce the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise no longer be comparable to a historic benchmark. We wanted the flexibility to respond to instances in which the clinical evidence and guidelines change and approved measures no longer reflect the most up-to-date clinical evidence and could even result in a practice that is harmful to patients. We finalized expanding the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we would allow scoring of the measure with a performance period truncation (to 9 months of data) or the complete suppression of the measure if 9 months of data are not available.

In the CY 2021 Quality Payment Program final rule, we finalized a consolidation of the CY 2018 and CY 2019 scoring flexibilities policy that allowed, beginning with the 2021 performance period/2023 MIPS payment year, truncation of the performance period or suppression of a quality measure if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we would assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we would suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted (85 FR 84898 through 84901).

In previous rules, we noted that we believe that there may be instances when there are changes after the final approval of quality measures including changes to the measure specification, or updates to coding that may lead to misleading results (85 FR 84899). Additionally, we believe that there may be instances in which there is an inadvertent omission of codes, or inclusion of deactivated codes in the measure specifications that do not have the correct status. Typically, codes that are contained within the measure specifications either have a reimbursable status or a non-reimbursable status that still allows processing for purposes of quality reporting programs. We have encountered instances where CMS has been alerted that codes have inadvertently received an inactive status which results in the associated codes not being processed and stored in the National Claims History (NCH) database and therefore not available for quality purposes. As the measure specifications are considered technical documents that include several fields such as, but not limited to: the numerator, denominator, measure description, denominator exclusions, clinical guidance statements, and codes relevant to how the measure should be captured. The measure specifications are finalized and published in coordination with the final rule, and prior to the start of the performance period. An inadvertent omission of codes, or inclusion of inactive codes in the measure specifications, may result in misleading results by affecting clinicians who submit the measure. In these instances, implementation errors could lead to misleading performance rates by failure to reflect accurate numerator and/or denominator values for calculation of the measure. These are not changes that occur during the performance period, but errors that would affect the performance period.

It recently came to our attention through Help Desk inquiries that Medicare Administration Carriers (MACs) were rejecting 2021 Part B Claims submissions for Quality Measure ID (QID) 001: Hemoglobin A1c (HbA1c) Poor Control (>9%) and QID 117 Diabetes: Eye Exam due to an inactive status for certain CPT II codes. The omission of these claims from the total denominator population of the measure could skew scores and lead to misleading results. We believe suppression of the measures is consistent with current § 414.1380(b)(1)(vii)(A). Information on the suppression of the Part B claims collection type of these measures for the 2021 MIPS performance period/2023 MIPS payment year was announced via the QPP listserv on July 1st, 2021. For more information please refer to our website *qpp.cms.gov*.

We propose to amend § 414.1380(b)(1)(vii)(A) to clarify our intended policy on instances in which we become aware of changes to the active or payable status of the codes and/or implementation errors included in the measure specifications as finalized that would lead to misleading results. Accordingly, we propose to revise § 414.1380(b)(1)(vii)(A) to change ''significant changes'' to ''significant changes or errors'' and to include the omission of codes or inclusion of inactive or inaccurate codes to provide that for each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to,

changes to codes (such as ICD–10, CPT, or HCPCS codes) or the active status of codes, the inadvertent omission of codes, or inclusion of inactive or inaccurate codes; changes to clinical guidelines; or measure specifications. We will publish on the CMS website a list of all measures scored under paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than data submission deadline at § 414.1325(e)(1).

We invite public comments on our proposal to provide scoring flexibilities in response to account for errors included in the finalized measures.

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017, CY 2018, CY 2019, CY 2020, and CY 2021 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, 84 FR 63014 through 63016, and 85 FR 84901 through 84904) for our previously established benchmarking policies.

In the CY 2017 QPP final rule (81 FR 77277 through 77282), we finalized that we would use performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or where we do not have comparable data from the baseline period, for which we would set the benchmarks using performance in the performance period. We defined the baseline period to be the 12-month CY that is 2 years prior to the performance period for the MIPS payment year. For example, for the CY 2022, the baseline period two performance periods prior would be the CY 2020 performance period (81 FR 77277). Additionally, we further clarified that CMS can establish benchmarks either by the applicable baseline or performance period in the CY 2019 PFS final rule (83 FR 59842), where we finalized the terminology change amending § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Because of the flexibility provided to MIPS eligible clinicians to allow for no data submission for the 2020 performance period (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1198/2020%20MIPS%20Automatic%20EUC%20Fact%20Sheet.pdf*), we may not have as representative of a sample of data as we would have had without the national PHE for COVID–19. Therefore, we want to revisit our benchmarking policy for the 2022 performance period/2024 MIPS payment year similarly to how we revisited the benchmarking policy for the 2021 performance period/2023 MIPS payment year (85 FR 84901 through 84902). We anticipate that we may have a gap in our data due to receiving fewer submissions for CY 2020, which could skew the benchmarking results. We believe this gap in data could result in different distributions of scores from what we normally see; thus, skewing the benchmarks when using CY 2020 data as the baseline for the CY 2022 performance period/2024 MIPS payment year. Additionally, we anticipate that only those not experiencing a hardship will submit data, thus skewing benchmarks much higher than normal. We ultimately, did not finalize this proposal for CY 2021 because analysis of the submitted data from the CY 2019 performance period/2021 payment period showed that it was suitable for use in calculating benchmarks. However, as we know from the events of 2020, we anticipate that the effects of the national PHE for COVID–19 may be more significant for the CY 2020 performance period.

For this reason, we consider two benchmarking options for the CY 2022 performance period/2024 MIPS payment year. We propose to use performance period benchmarks for the CY 2022 performance period/2024 MIPS payment year in accordance with § 414.1380(b)(1)(ii). As discussed in the CY 2021 PFS final rule (85 FR 84902), this would mean that benchmarks for the CY 2022 performance period/2024 MIPS payment year are based on the actual data submitted during the CY 2022 performance period. Last year, we received comments supportive of our proposal to use performance period benchmarks citing that the performance period benchmarks would capture any changes in care due to the national PHE for COVID–19 and avoid unfairly penalizing practices for variation in performance compared to data from prior to the national PHE for COVID–19 (85 FR 84902 through 84903). We also received comments that opposed the use of performance period benchmarks, as clinicians would not have advance notice of performance targets. As a result, we are also considering and seeking feedback as an alternative to performance period benchmarks, utilizing the historic benchmarks from the 2021 MIPS performance period (which are based on submissions for CY 2019 MIPS performance period/2021 MIPS payment year) for the CY 2022 performance period/2024 MIPS payment year. We believe that this option would allow clinicians to continue to receive advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures for the CY 2022 performance period/2024 MIPS payment year. However, we remain concerned that utilizing outdated data could also potentially result in distributions of scores used for benchmarks that no longer reflect the standard of care especially as care changes in response to the public health emergency. Additionally, any new or substantively changed measures in the CY 2022 performance period/2024 MIPS payment year will lack a benchmark, as would measures that were suppressed in the CY 2019 performance period/2021 MIPS payment year alternate baseline period. We will analyze the CY 2020 performance period data and compare the distribution of the CY 2020 performance period data to that of previous years to assess if we can in fact use data from the CY 2020 performance period for benchmarks for the CY 2022 performance period/2024 MIPS payment year and if not, evaluate the suitability of the alternatives.

Additionally, we propose to expand the definition of the baseline period. In instances in which a measure is suppressed 2 performance periods prior in the standard baseline period and cannot be used to calculate a benchmark, we propose to use the data from 3 performance periods prior to calculate benchmarks in the event that a performance period benchmark cannot be calculated. This would mean that for the CY 2022 performance period/2024 MIPS payment year, if a measure was suppressed in the 2020 performance period and a performance period benchmark could not be calculated using the 2022 performance period data because it was not reported by 20 different clinicians or groups that met data completeness and case minimum requirements, we would calculate a benchmark from performance period data from CY 2019. If a measure had undergone a substantive change or was also suppressed in the baseline period 3 performance periods prior, we would not use it to calculate benchmarks and the measure would be subject to our scoring policies for class 2 measures. We would not use benchmarks calculated from performance periods that are older than 3 performance periods prior. We believe it is important to continue using the most up-to-date

data to drive clinical quality improvement. We believe that this policy will reduce burden to clinicians and allow them to continue to have performance targets in the event that a measure is suppressed.

We invite public comments on our intent to use performance period benchmarks for the CY 2022 performance period and to expand the baseline period to 3 performance periods prior for measures that are suppressed two performance periods prior. Table 47 reflects a summary of the benchmarking hierarchy as a result of this proposal.

TABLE 47: Quality Performance Category: Proposed Benchmarking Hierarchy

Policy Hierarchy	Baseline period used to calculate Benchmark	Condition
1	Historical Baseline Period: Two Performance Periods prior to the applicable performance period	A benchmark can be calculated from the historical baseline period defined as two performance periods prior to the applicable performance period.
2	Performance Period Benchmark	A benchmark cannot be calculated from the historical baseline period, but 20 or more clinicians report on a measure and meet or exceed the case minimum of 20 cases during the performance period.
3	Alternate Historical Baseline Period: Three Performance periods prior to the applicable performance period	A measure is suppressed in the historical baseline period two years prior to the applicable performance period and a performance period benchmark cannot be calculated, but a benchmark can be calculated from the alternate historical baseline period defined as three performance periods prior to the applicable performance period can be calculated because the measure had not undergone a substantive change in the time since the data was collected or been suppressed in the baseline period.
4	No baseline: Subject to class 2 scoring policy	A benchmark cannot be calculated from the historical baseline period, the performance period, or the alternate baseline period.

(iii) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1)(i) for more details on our policies for scoring performance on quality measures (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, 84 FR 63011 through 63019, and 85 FR 84906 through 84907).

(A) Scoring Measures Based on Achievement

We previously established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as each administrative claims measure. MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that we would revisit the 3-point floor in future years. For the 2021 performance period/2023 MIPS payment year, we maintained the application of the 3-point floor for each measure that can be reliably scored against a benchmark.

For the 2022 performance period/2024 MIPS payment year, we propose to remove 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points. We are scoring from 1–10 for clinicians with a performance rate greater than 0% for non-inverse measures or lesser than 100 percent for inverse measures in accordance with our original intent outlined in the CY 2017 Quality Payment Program final rule (81 FR 77282). As we move towards the MVP framework discussed the CY 2021 PFS final rule (85 FR 84904), we are moving towards a simplified scoring standard in which we can score quality measures from 1 to 10 for measures in MVPs and as such will amend the MIPS program to begin promoting this alignment. As a result, we previously discussed that we would wait until there is further policy development under the MVP framework before proposing to remove the 3-point floor (85 FR 84904). However, with the delay in the implementation of MVPs, we will begin the transition to MVPs by removing policies established on the transition years of MIPS. We have signaled through rulemaking for several years that we would revisit policies established during the transition years of the program from the legacy programs to MIPS. As the legacy programs have been sunsetted for many years now, we believe that it is appropriate to transition the MIPS program to its mature state. Additionally, we believe that transitioning MIPS to its mature state will serve as a transition period to allow clinicians to adjust to the simplified scoring standard that we will be using in MVPs.

Accordingly, we propose to revise § 414.1380(b)(1)(i) to add beginning the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will receive between 1 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340.

We invite public comment on our proposal to remove the 3-point floor for each measure that can be reliably scored against a benchmark for the 2022 performance period/2024 MIPS payment year.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement (84 FR 63012).

In the 2017 QPP final rule (81 FR 77288) and the 2018 QPP final rule (82 FR 53727), we identified ''classes of measures'' which were intended to characterize measures for the ease of discussion. Class 1 measures are measures that can be scored based on performance because they have a benchmark, meet the case minimum and data completeness requirements. Class 2 measures are measures that cannot be scored based on performance because they do not have a benchmark or do not meet the case minimum which is generally 20 cases. Class 3 measures are measures that do not meet the data completeness requirement. We also noted that policies for Class 2 and Class 3 measures would not apply to measures submitted with the CMS Web Interface or administrative claims-based measures.

We propose to modify how we score these measures within MIPS, as we consider policies for transitioning to MVPs. For class 2 measures, for the 2022 performance period/2024 MIPS payment year, we propose to remove special scoring policies for measures that meet the data completeness requirement but do not have a benchmark, due to fewer than 20 individual clinicians or groups adequately reporting the measure, or meet the case minimum requirement except in the case of small practices, for which we will maintain the 3-point floor. Practices of other sizes will now receive zero points.

As we move to MVPs, we are seeking to simplify scoring by removing transition policies. To encourage complete and meaningful reporting, we cannot continue to award measure achievement points for measures that cannot be reliably scored against a benchmark. In a quality measurement program such as MIPS, it is imperative that we are able to reliably measure performance on clinical quality measures to achieve the goals of the program and incentivize clinicians that are providing the high-quality care. However, we remain concerned that it may be harder to reach case minimums for smaller practices and as such are maintaining the three-point floor policy for small practices. We believe that measure selection that is better reflective of the care most commonly provided in a practice will increase the value of the program by allowing us to score for achievement in clinical quality and subsequently drive changes in performance on clinical quality measures.

Measure benchmarks are posted in advance of the MIPS performance period and can be used to drive clinician measure selection. While not all measures relevant to a clinician's practice may have a historic benchmark posted, clinicians have the option to make informed decisions about their participation in the MIPS program. Additionally, we believe that while clinicians do not have control over the case volume and mix that their practices treat, under normal circumstances, they can anticipate which measures would be most reflective of the care generally provided by said practices. Scoring 3 points for class 2 measures was established as a policy during the transition years of the program, when the performance threshold was 3 points and scoring 3 points for quality would help clinicians transitioning to the program without receiving scores for poor performance. The intent of the policy was to provide time for clinicians to acclimate to the scoring standard before being held fully accountable for their participation in the program (81 FR 77287). As we believe we have provided sufficient time for clinicians to acclimate to our reporting requirements and scoring practices, we believe that we can hold clinicians accountable for their meaningful participation in the program.

We remain concerned about that case minimums and the availability of a benchmark are in some instances out of the control of the clinician, but believe that clinician choice of measure allows us to move forward with this option. We note that we also have policies in place to account for the calculation of a performance period benchmark if a historical benchmark is unavailable. Simulations of the effects of this policy show minimal effects of removing the 3-point floor as described above, with only a 0.4 point decrease in median quality performance category score and 0.2 point decrease in mean performance quality performance category score when compared to a baseline score that maintains the previously finalized class 2 measure scoring policy (section VII.F.18 of this proposed rule). We considered other approaches to address this issue such as a denominator reduction for class 2 measures; however, we remain concerned over the potential for gaming under this approach, such as where a clinician only selects class 2 measures resulting in their quality performance category score being reweighted.

We do not want this policy to discourage the reporting of new measures in the program because they may lack a benchmark or fail to meet the case minimum requirement. For this reason, we are proposing a 5-point floor for new measures in the program for all collection types for their first 2 years in the program, as well as a new class for these measures. Measures in either their first or second performance period in the program will be classified as class 4 measures. Measures that can be reliably scored against a benchmark because they meet data completeness requirement can have a performance period benchmark calculated, and meet case minimum requirements will be considered class 4a and scored from 5 to 10 measure achievement points. In the event that a measure cannot be reliably scored against a benchmark because it lacks a benchmark or does not meet case minimum, but meets the data completeness requirement, it will be considered class 4b and receive a score of 5. Measures that cannot be scored because they do not meet the data completeness requirement will remain subject to the class 3 measure policy and receive a score of 0 for clinicians other than small practices, while small practices will continue to receive 3 points.

We believe that a 5-point floor for new measures will allow us to introduce new, applicable measures into the program, by reducing the burden to clinicians in selecting them. We believe that this policy is responsive to stakeholder concerns that new measures run the risk of lacking enough data to have a benchmark and clinicians earning only 3 points according to the current policy on measures that cannot be reliably scored against a benchmark. We believe that the possibility of earning 5 points for a measure that lacks a benchmark would not unfairly penalize clinicians who report on new measures. Additionally, clinicians have the possibility of earning up to 10 points with the lowest possible score of 5. The 5-point floor will only be in place for a measure's first 2 years in the program to ease their transition, and will be scored in accordance with policies for standard class 1, 2, and 3 measures thereafter, to maintain a simplified scoring methodology. In the CY 2017 Quality Payment Program final rule, we received comments of support on our proposal to provide a scoring floor for new

measures citing that a scoring floor for new measures would encourage clinicians to report new measures and prevent gaming. Commenters were also supportive other approaches to reducing the burden of reporting new measures such as reducing the weight of new measures in the performance category score (81 FR 77281).

Accordingly, we propose to revise § 414.1380(b)(1)(i)(A)(*1*) to provide that except as provided in paragraph (b)(1)(i)(A)(*2*) and (*3*) of this section, for the 2017 through 2021 CY performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning within the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians other than small practices receive 0 measure achievement points for each such submitted measures and small practices receive 3 measure achievement points.

We also propose to add the policy for new measures at § 414.1380(b)(1)(i)(C)(*1*) to provide that beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians receive between 5 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340. We also propose to add a policy at § 414.1380(b)(1)(i)(C)(*2*) to provide that for purposes of this section ''new measures'' means a quality measure this is in its first 2 years in the program.

We invite public comments on our proposal to modify the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement for the MIPS 2024 payment year and to introduce a 5-point scoring floor for new measures in for their first 2 years in the program. Table 48 reflects a summary of our proposed policies.

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TABLE 48: Quality Performance Category: Scoring Policies for the CY 2022 MIPS Performance Period*

Measure type	Description	Current Scoring Policy for CY 2021	Proposed Scoring Policy for CY 2022
Class 1	Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Meets case minimum; and (3) Meets the data completeness standard (generally 70 percent for 2022.)**	3-10 measure achievement points based on performance compared to the benchmark	1 to 10 measure achievement points based on performance compared to the benchmark.
Class 2	Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark; and (2) Meets case minimum.	3 points	MIPS eligible clinicians other than small practices will receive zero points for this measure. Small practices will continue to receive 3 points.
Class 3	Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum.	MIPS eligible clinicians other than small practices will receive zero points for this measure. Small practices will continue to receive 3 points.	No change
New Measures: Class 4	Measures that are in their first two performance periods in the MIPS program that meet the data completeness requirement, but (1) May lack a benchmark (2) May not meet case minimum	No Policy	(a) For measures that can be reliably scored against a benchmark: 5-10 measure achievement points (b) For measures that cannot be reliably scored against a benchmark because they lack a benchmark or do not meet case minimum: 5 points

*The Class 2 and 3 measure scoring policies are not applicable to Web Interface and administrative claims-based measures.

**We refer readers to § 414.1335(a)(3) for our policy on data completeness.

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(iv) Scoring for MIPS Eligible Clinicians That Do Not Meet Quality Performance Category Criteria

In the CY 2018 Quality Payment Program final rule (82 FR 53732), we finalized that, beginning with the 2019 performance period/2021 MIPS payment year, we will validate the availability and applicability of quality measures only with respect to the collection type that a MIPS eligible clinician utilizes for the quality performance category for a performance period, and only if a MIPS eligible clinician collects via claims only, MIPS CQMs only, or a combination of MIPS CQMs and claims collection types. We will not apply the validation process to any data collection type that the MIPS eligible clinician does not utilize for the quality performance category for the performance period. We sought comment on how to modify the validation process for the 2019 performance period/2021 MIPS payment year when clinicians may submit measures collected via multiple collection types.

In the CY 2019 PFS final rule (83 FR 59847), we finalized a proposal to modify our validation process to provide that it only applies to MIPS CQMs and the claims collection type, regardless of the submitter type chosen. For example, this policy would not apply to eCQMs even if they are submitted by a registry. We noted that a MIPS eligible clinician may not have available and applicable quality measures. If we are unable to score the quality performance category, then we may reweight the clinician's score according to the reweighting policies.

In this year's rule, we are proposing to modify our validation process to provide that it only applies to MIPS CQMs or the Part B claims collection type, but it will not apply in instances when a MIPS eligible clinician submits for both collection types. Currently, very few reporters report for a combination of Part B claims and MIPS CQMs. In CY 2020, of submissions with less than 6 measures, only 0.08 percent of individual submissions and 0.3 percent of group submissions included a combination of Part B claims and other submission types. In CY 2019, of submissions with less than 6 measures, only 0.094 percent of individual submissions and 0.07 percent of group submissions included a combination of Part B claims and other submission types. We see that reporting using both collection types is an option very few clinicians have chosen to utilize, and consequently believe that the associated costs for validation of a combination of the both the Part B claims based and MIPS CQM collection types is too great in these instances. To align with this reality that very few clinicians submit data in this manner, we are proposing to update our policy.

We invite public comments on our proposal to modify our validation process to provide that it only applies to MIPS CQMs or the claims collection type and not a combination of the two.

(v) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to § 414.1380(b)(1)(iv) for our previously finalized policies regarding the identification of topped out measures and § 414.1380(b)(1)(iv)(B) for our finalized policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we will identify topped out measures in the benchmarks published for each Quality Payment Program year. Under § 414.1380(b)(1)(iv)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727).

We noted in the CY 2021 PFS proposed rule (85 FR 50307) that we intended to use performance period benchmarks for the 2021 performance period/2021 MIPS payment year, which would mean we would not be able to publish measures that are topped out prior to the 2021 MIPS performance period. As discussed in that proposed rule (85 FR 50309), this also means we would not be able to identify those that have been topped-out for 2 or more consecutive years for purposes of the topped out scoring of 7 measure achievement points. As we are intending to use performance period benchmarks again for the 2022 performance period/2024 MIPS payment year, these problems would occur again. We believe it is still important to retain a topped-out scoring cap of 7 measure achievement points so that clinicians have incentives to pick alternate measures that are not topped out. We also believe that if a measure is not topped out in the 2022 performance period benchmark, then it should have the ability to achieve up to 10 measure achievement points.

In this year's proposed rule, we are proposing to use performance period benchmarks again and subsequently need to the topped out measure lifecycle to account for this. Therefore, in the event that we finalize the use of performance period benchmarks for the CY 2022 performance period/2024 MIPS payment year, as an exception from the general rule at § 414.1380(b)(1)(iv)(B), we propose at paragraph (b)(1)(iv)(B)(*1*) to provide that for the CY 2022 MIPS performance period/2024 MIPS payment year, MIPS eligible clinicians receive no more than 7 measure achievement points for each measure (except for measures in the CMS Web Interface) for which the applicable benchmark is identified as topped out for 2 or more consecutive years based on the historical benchmarks published for the CY 2021 MIPS performance period and continues to be identified as topped out based on the performance period benchmarks published for the CY 2022 MIPS performance period/2024 MIPS payment year.

We believe these two criteria collectively would provide clinicians the information to know prior to the CY 2022 performance period/2024 MIPS payment year which measures would have the topped-out scoring applied but would also account for the scenario where a measure is no longer topped out. We would not limit the number of measure achievement points for measures that have not been topped out for at least 2 years as published in the 2021 MIPS performance period/2023 MIPS payment year historical benchmarks.

We invite public comments on our proposal to apply the 7 measures achievement point cap to measures that meet the two criteria.

(vi) Minimum Case Requirements

We refer readers to § 414.1380(b)(1)(iii) for our previous finalized policies regarding case minimum requirements for the quality performance category, which establishes the case minimum requirement threshold at 20 cases for quality measures, with the exception of administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). As more measures are introduced under MIPS, there may be measures, similar to the administrative claims-based measures, that warrant a different case minimum requirement from the other quality measures. In Table Group A of Appendix 1 of this proposed rule, we are proposing to add the following quality measure starting with the 2022 MIPS performance period: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO–PM), which uses a comprehensive and parsimonious set

of 11 patient-reported items to assess the broad scope of primary care. In order to achieve the appropriate reliability of the measure—the survey results (adequate number of surveys to provide an accurate representation of the MIPS eligible clinician, group, subgroup, virtual group, and APM Entity), for each MIPS eligible clinician, group, subgroup, virtual group, and APM Entity, a minimum of 30 PCPCM PROM instruments per clinician are needed for submission of this measure. For MIPS eligible groups, subgroups, virtual groups, and APM Entities with 5 or more clinicians, a minimum of 150 PCPCM PROM instruments per TIN for each site/location associated with the clinicians' part of the group, subgroups, virtual groups, and APM Entities are needed for submission of this measure. For TINs with a composition of multiple specialty practices at one site/location, a minimum of 150 PCPCM PROM instruments per specialty practice within a TIN are needed for submission of this measure. If the MIPS eligible group, subgroup, virtual group, and APM Entity with 5 or more clinicians encompasses multiple sites/locations, each site/location would need to meet the PCPCM PROM instruments requirements as noted above. To allow for the reliable implementation of PCPCM PRO–PM under MIPS, such measure requires a case minimum that exceeds 20 cases.

With more measures being introduced under MIPS that warrant differing case minimum requirements (other than administrative claims-based measures), we are proposing to modify our minimum case requirements policy that would broaden the type of measures (to not only include administrative claims-based measures) having an exception for meeting the minimum case requirement threshold of 20 cases and provide for a measure-specific case minimum requirement for measures identified and determined on a case-by-case basis by CMS. For each measure with a measure-specific case minimum, the minimum case requirement is specified in the annual list of MIPS measures. Specifically, we are proposing to amend § 414.1380(b)(1)(iii) to reflect that, except as otherwise specified in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

We seek public comment on our proposal to modify the minimum case requirement policy that expands the exception to meeting the minimum case requirement threshold of 20 cases to measures with measure-specific case minimum requirements identified and determined by CMS.

We request feedback on our proposal.

(vii) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for our previously finalized policies regarding incentives to report high priority measures. In the CY 2017 Quality Payment Program final rule (81 FR 77293), we established the scoring policies for high priority measure bonus points to encourage the selection of additional high-priority and outcome measures that impact beneficiaries and were closely aligned to our measurement goals. In the CY 2019 PFS final rule (83 FR 59850), we discontinued awarding measure bonus points to CMS Web Interface reporters for reporting high priority measures since CMS Web Interface reporters have no choice in measures.

We stated in the CY 2019 PFS proposed and final rules (83 FR 35950, 59851) that as part of our move towards fully implementing high value measures, we believe that bonus points for high priority measures for all collection types may no longer be needed. We noted in the CY 2019 PFS final rule (83 FR 59851) that measure bonus points were created as transition policies which were not meant to continue through the life of the program. We believe with the finalized framework for transforming MIPS through MVPs (84 FR 62948), we will find ways in the future to emphasize high priority measures without needing to incentivize with bonus points.

In this proposed rule, we propose to end the high-priority measure bonus points. As we move to MVPs we are simplifying our scoring by ending transition policies that were established in the initial years of the program. We have signaled for many years now that this policy was temporary and would be removed from the program. As we transition to a new state, we anticipate that there will no longer be a need to incentivize high-priority measures by usage of bonus points in MIPS and MVPs as we increase the share of high-priority measures in the program.

We propose to end measure points for reporting high priority measures beginning the 2022 performance period/2024 MIPS payment year. Accordingly, we propose to revise § 414.1380(b)(1)(v)(A) to provide that for the 2017 through 2021 performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus points.

We invite public comments on our proposal to end measure points for reporting high priority measures beginning the 2022 performance period/2024 MIPS payment year.

(viii) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii)(I) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT and qualified clinical data registries. Section 1848(q)(5)(B)(ii)(II) of the Act requires that the Secretary shall treat such clinicians as satisfying the clinical quality measures reporting requirement described in section 1848(o)(2)(A)(iii) of the Act if they report such measures through the use of such EHR technology for a given performance period. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for using CEHRT for end-to-end electronic reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting. We believe that with the framework for transforming MIPS through MVPs discussed in the CY 2020 PFS proposed rule (84 FR 40739) and the CY 2021 PFS proposed rule (85 FR 50279 through 50285), we will find ways to encourage the use of CEHRT for reporting quality measures without needing to incentivize the use of CEHRT for end-to-end electronic reporting with bonus points. In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged stakeholders to consider electronically specifying their quality measures as eCQMs, to encourage clinicians and groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the life of the program.

In this proposed rule, we propose to end measure bonus points for end-to-end electronic reporting. As we move to MVPs we are simplifying scoring by removing many of the transition policies that we established in the early years of the program. We believe it is imperative

to remove transition policies in order to develop a stronger MVP program and promote alignment between MIPS and MVPs. As stated in previous rulemaking, we are working to develop ways to encourage the use of CEHRT for electronic reporting without offering measure bonus points. Measure bonus points act to introduce scoring inflation into the program and preclude our ability to accurately compare clinicians' clinical quality. As the program works to focus on the quality of care provided to beneficiaries, we intend to score for performance on measures and not for reporting. Additionally, we believe that we can fulfill the statutory requirement at sections 1848(q)(5)(B)(ii)(I) of the Act to encourage the usage of certified electronic health record technology (CEHRT), through other means. As a program and across the Department of Health and Human Services, we are working towards the goal of all measures within MIPS being digital by 2025 through a movement towards the inclusion of more digital quality measures (dQMs), emphasizing approaches to electronic data sharing that utilize the FHIR standard. As part of these approaches we intend to further leverage the use of electronic reporting from CEHRT for all quality measurement completed in the MIPS program including measurement and reporting facilitated by third party intermediaries such as QCDRs and plan to further address this issue through rulemaking in future years. We are also giving preference to dQMs including eCQMs in our annual call for measures. More information on dQMs and the FHIR standard is available in section IV.A. of this proposed rule, information on the call for measures and CMS measurement needs and priorities is available at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1313/2021%20Call%20for%20Measures%20and%20Activities%20Toolkit.zip*, and *https://www.cms.gov/files/document/cms-measurement-priorities-and-needs.pdf*, respectively. Furthermore, over the past few years, we have reduced the availability and limited who can submit data for the Medicare Part B claims collection type to only small practices. We note that the Medicare Part B claims collection type is not an electronic means of submission. We invited comments on other methods we can use to encourage the use of CEHRT for electronic reporting.

Accordingly, we proposed to add the policy at § 414.1380(b)(1)(v)(B) to provide that for the 2017 through 2021 performance period/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary. Beginning in the 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus points for submitting using end-to-end electronic reporting.

We invite public comments on our proposal to end measure bonus points for end-to-end electronic reporting beginning in the 2022 performance period/2024 MIPS payment year.

(ix) Improvement Scoring for the MIPS Quality Performance Category Score

We refer readers to § 414.1380(b)(1)(vi)(C)(*4*) for more on our policy stating that for the 2020 through 2023 MIPS payment years, for the purpose of improvement scoring, we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

In this proposed rule, we propose to continue our previously established policy for improvement scoring for the 2022 performance period/2024 MIPS payment year and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 through 2023 MIPS payment years'' and adding in its place the phrase ''beginning the 2018 performance period/2020 MIPS payment year'' to indicate that for each MIPS payment year after 2020, we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Specifically, for the 2022 performance period/2024 MIPS payment year, we would compare the MIPS eligible clinician's quality performance category achievement percent score for the 2022 performance period/2024 MIPS payment year to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance score less than or equal to 30 percent for the 2021 performance period/2023 MIPS payment year.

We invite public comments on our proposal to assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year for the 2022 performance period/2024 MIPS payment year.

(d) Cost Performance Category

(i) Scoring Flexibility for Changes That Impact Cost Measures During the Performance Period

We refer readers to § 414.1380(b)(2) for our policies regarding scoring for the cost performance category and to previous rules where these policies were finalized, including the CY 2017 Quality Payment Program final rule (81 FR 77308 through 77311), the CY 2018 Quality Payment Program final rule (82 FR 53748 through 53752), the CY 2019 PFS final rule (83 FR 59856), and the CY 2021 PFS final rule (85 FR 84877 through 84880). In § 414.1380(b)(2)(v), we finalized that a cost performance category score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

We have identified that there is a need for additional flexibility in calculating the scores for cost measures to account for the impact of changing conditions that are beyond the control of MIPS eligible clinicians and groups. This flexibility would allow us to ensure that clinicians are not impacted negatively when performance is affected not due to the care provided, but due to external factors. Thus, beginning with the 2022 MIPS performance period/2024 MIPS payment year, we propose a policy to provide scoring flexibility in instances where changes during a performance period impede the effective measurement of resource use. We believe that there may be instances when there are rapid or unprecedented changes to the delivery of healthcare services that are reflected in administrative claims data used to calculate cost measures. An example of the type of external factor that could affect cost measurement is the PHE for COVID–19. We refer readers to section IV.A.3.e.(2)(b)(ii)(A) of this proposed rule, where we summarize our assessment of the impact of COVID–19 on the calculation of cost measure scores for the 2020 performance period. In this discussion, we conclude that due to the unique and rapid changes to healthcare in the COVID–19 pandemic, which significantly affected service utilization and the underlying data used

to calculate cost measures, we cannot reliably calculate scores for the cost measures that adequately capture and reflect clinician performance for 2020. This example demonstrates that the assessment of costs could be impeded by substantial changes to clinical practice and service utilization, and result in misleading or inaccurate results.

We will determine whether such external changes impede the effective measurement of resource use by considering factors including: The extent and duration of the changes, and the conceptual and empirically tested relationship between the changes and each measure's ability to accurately capture clinician cost performance. Empirical testing could include assessing whether there are rapid or unprecedented changes to patient case volume or case mix, and the extent to which this could lead to misleading or inaccurate results. We note that substantial changes in service utilization may not impede our ability to accurately calculate a cost measure score. Consider for example the case of a hypothetical measure that includes the cost of a series of procedures to treat the condition being measured. Due to advances in clinical knowledge, the procedures are declared to no longer be appropriate to treat the condition during a performance period. This would hypothetically lead to rapid and substantial changes in the services captured in the measure in that performance period; however, these changes would not necessarily lead to misleading or inaccurate results as the measure would be appropriately capturing the costs of care for that condition and appropriately reflecting changes in clinician practice. We would assess this empirically for each measure, as we believe that even widespread external changes to service utilization could have a range of different impacts across measures as they focus on diverse types of care. For example, a hypothetical national shortage of blood products may lead to the suspension of elective surgeries. This may not affect the care patterns for a particular outpatient screening or preventative care procedure, meaning that a hypothetical cost measure focused on that outpatient procedure would still accurately reflect clinician cost performance.

While we can monitor the impact of these changes during the performance period, we note that there is an inherent delay between the time we can identify trends in administrative claims data and when we can test for potential impact on the cost measures, due to the claims run-out period necessary to ensure that data included in our analyses reflect final claims for all services in episodes. To ensure sufficient case volume, we expect that we would not be able to properly test the full impact of external changes on the cost measures until after the end of the performance period in which the changes occurred. Thus, we would not be able to determine whether a cost measure should be suppressed due to changes in the performance period until after the completion of the performance period. To allow sufficient time for claims data query and investigatory work to test for potential impacts on cost measure calculations, we expect that we would reach a conclusion as to whether a cost measure should be suppressed and notify clinicians affected by the suppression no later than when performance feedback is issued for the performance period. We believe this would not put undue burden on clinicians since cost measures are calculated by CMS using administrative claims data without any additional data submission by clinicians.

Accordingly, we propose to add § 414.1380(b)(2)(v)(A) to provide that beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(A), ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. Significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

We seek comments on this proposal.

(e) Promoting Interoperability Performance Category

For our previously established policies regarding scoring the Promoting Interoperability performance category, we refer readers to § 414.1380(b)(4), the CY 2017 Quality Payment Program final rule (81 FR 77216 through 77227), the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53670), the CY 2019 PFS final rule (83 FR 59785 through 59796), the CY 2020 PFS final rule (84 FR 63020) and the CY 2021 PFS final rule (85 FR 84893 through 84894). We also refer readers to § 414.1375 and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), the CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), the CY 2019 PFS final rule (83 FR 59785 through 59820), and the CY 2021 PFS final rule (85 FR 84886 through 84895 for our previously established policies regarding the Promoting Interoperability (formerly the advancing care information) performance category generally.

In the CY 2019 PFS final rule, we established a new performance-based scoring methodology for the Promoting Interoperability performance category that applies beginning with the 2019 performance period/2021 MIPS payment year (83 FR 59787 through 59796). The scoring methodology is codified at § 414.1380(b)(4)(ii); however, the regulation text refers only to the 2021 and 2022 MIPS payment years, and does not mention subsequent years. We are proposing to revise § 414.1380(b)(4)(ii) for consistency with the previously established policy, by indicating that the methodology applies beginning with the 2019 MIPS performance period/2021 MIPS payment year and continuing to subsequent years. We are proposing to revise § 414.1380(b)(4)(ii) to remove ''for the 2021 and 2022 payment years'' and add in its place ''beginning with the 2019 performance period/2021 MIPS payment year'' and remove the word ''six'' to provide that beginning with the 2019 performance period/2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required measures and any applicable bonus scores, not to exceed 100 points.

In addition, for the 2020 performance period/2022 MIPS payment year, each optional measure in the Promoting Interoperability performance category was worth five bonus points (84 FR 63003), and for the 2021 performance period/2023 MIPS payment year, each optional measure was worth ten bonus points (85 FR 84894). In section IV.3.d.(4)(c)1. of this proposed rule, we are proposing that the Query of Prescription Drug Monitoring Program measure would be worth 10 bonus points, and in section IV.3.d.(4)(c)3 of this proposed rule, we are proposing that submission of a ''yes'' for the Public Health Registry Reporting measure or the Clinical Data Registry Reporting measure or the Syndromic Surveillance Reporting measure would be worth 5 bonus points. To reflect these policies, we are proposing a change to

§ 414.1380(b)(4)(ii)(C) to reflect that the optional measures are worth five or ten bonus points, as specified by CMS.

We invite public comments on our proposal to make these revisions.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for each MIPS eligible clinician, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, and CY 2021 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917 respectively) on final score calculations, performance category weights, reweighting the performance categories, and the complex patient bonus.

As described in more detail in the following sections, we:

- Propose to continue doubling the complex patient bonus for the CY 2021 MIPS performance period/CY 2023 MIPS payment year, as was previously finalized with a cap of 10 bonus points for the CY 2020 MIPS performance period/CY 2022 MIPS payment year (85 FR 50311).
- Propose to revise the complex patient bonus formula, which currently provides a bonus to all MIPS eligible clinicians, groups, virtual groups, and APM entities who submit data for at least one MIPS performance category, so that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year the complex patient bonus better target clinicians who treat a higher caseload of more complex and high-risk patients.
- Request comment on potential circumstances where we may not be able to reliably calculate a score for any of the cost measures as described under § 414.1380(c)(2)(i)(A)(*2*). Additionally, we note that we are reweighting the cost performance category for the CY 2020 MIPS performance period/CY 2022 MIPS payment year because we have concluded there are not sufficient measures and activities applicable and available for us to score any clinicians on performance due to the national PHE for COVID–19.
- Propose to continue performance category weight redistribution policies finalized for the CY 2022 MIPS performance period/CY 2024 MIPS payment year.
- Propose policies for redistributing the weight of the performance categories for small practices.
- Clarify how our application-based and automatic extreme and uncontrollable circumstances policies intersect.
- Propose a new policy to determine the MIPS final score for clinicians and groups who are eligible for facility-based measurement.

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS; and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the 2021, 2022, and 2023 MIPS payment years (83 FR 59870, 84 FR 63023, and 85 FR 84910, respectively). Additionally, we finalized for the 2022 MIPS payment year at § 414.1380(c)(3)(iv) that the complex patient bonus will be calculated under the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value will then be multiplied by 2 (85 FR 84911 through 84913). We refer readers to these final rules for additional details on the background, statutory authority, policy rationale, and previously finalized calculation of the complex patient bonus.

We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. The overall goal, when considering a bonus for complex patients, is two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We used the term ''patient complexity'' to consider a multitude of factors that describe and have an impact on patient health outcomes; such factors include the health status and medical conditions of patients, and social risk factors. We believe as the number and intensity of these factors increase for a single patient, the patient may require more services, more clinician focus, and more resources to achieve health outcomes similar to those who have fewer factors. In developing the policy for the complex patient bonus, we assessed whether there was a MIPS performance discrepancy by patient complexity using two well-established indicators in the Medicare program: Medical risk as measured through Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients that is dually eligible for Medicare and Medicaid (82 FR 53771 through 53776).

(ii) Complex Patient Bonus for the CY 2021 MIPS Performance Period/CY 2023 MIPS Payment Year

In this section of the proposed rule, we are proposing to modify the complex patient bonus for the CY 2021 MIPS performance period/CY 2023 MIPS payment year in response to the PHE for COVID–19. In the CY 2020 PFS final rule, we finalized a policy to continue the complex patient bonus for the CY 2020 performance period/CY 2022 MIPS payment year (84 FR 63021 through 63023). However, due to the national PHE for COVID–19 during performance period 2020, we noted in the CY 2021 PFS proposed rule that we need to re-evaluate the previously established policy for the complex patient bonus for the CY 2020 MIPS performance period/ 2022 MIPS payment year (85 FR 50311). We refer readers to the CY 2021 PFS proposed rule (85 FR 50311 through 50313) for further details on how the PHE for COVID–19 impacts care delivery both directly and indirectly. We acknowledged there are direct effects of COVID–19 for those patients who tested positive for SARS–CoV–2 and indirect effects of COVID–19 for other patients whose care was impacted because of the PHE, including increased complexity and barriers such as postponing care, accessing care in a different way (for example, via telecommunications), and disruptions to

lab results and medications, which are not accounted for in our existing final score calculations using these complexity indicators.

Considering both these direct and indirect effects, we finalized § 414.1380(c)(3)(iv) (85 FR 84913), under which the complex patient bonus is calculated for the CY 2022 MIPS payment year pursuant to the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value is then multiplied by 2 but cannot exceed 10.0. The doubled numerical value (subject to the 10-point cap) is added to the final score.

We believe we have made significant progress against COVID–19. As noted by the Centers for Disease Control and Prevention (CDC), the number of COVID–19 cases are predicted to decrease through the week of July 17th, 2021 in the United States and territories.[235] As of June 1, 2021, the number of daily new cases in the United States is at a similar level compared to the number of daily new cases during this time last year.[236] While we are encouraged by these results, we believe that there may be some residual direct and indirect effects from the PHE that could affect the CY 2021 MIPS performance period/CY 2023 MIPS payment year. In particular, for the first quarter, we had high COVID cases in multiple regions.[237] Additionally, we cannot quantify the effect of beneficiaries who delayed care because of the PHE and are now seeking care.

Because of the concerns of the direct and indirect effects of the COVID–19 PHE, we propose to continue doubling the complex patient bonus as described at § 414.1380(c)(3)(iv) for the CY 2023 MIPS payment year, and we propose corresponding revisions to the regulation text at § 414.1380(c)(3)(iv). The doubled numerical value (subject to the 10-point cap) would be added to the final score. Since the COVID–19 cases and deaths have decreased throughout the year, we considered applying a smaller multiplier (like 1.5 for a cap of up to 7.5 points) or to not apply a multiplier at all. However, we believe doubling the complex patient bonus is appropriate given the continuation of the national PHE for COVID–19 into the 2021 MIPS performance period, the potential direct and indirect effects of COVID–19 on care delivery and care postponement, and additional uncertainties. We seek comment on this proposal and whether a different multiplier should be applied as we plan to consider the options based on public comment.

(iii) Complex Patient Bonus Beginning With the CY 2022 MIPS Performance Period/CY 2024 MIPS Payment Year

(A) Complex Patient Bonus Background and Analysis

As discussed in the CY 2021 PFS final rule (85 FR 84908), we intended the complex patient bonus as a short-term solution to address the impact patient complexity may have on MIPS scoring. However, during the development of the CY 2021 PFS final rule, we did not have sufficient information available to develop a long-term solution to account for patient risk factors in MIPS that we could include as a finalized policy for the CY 2021 MIPS performance period/CY 2023 MIPS payment year. In the CY 2020 PFS proposed and final rules, we considered whether newly available data from the Quality Payment Program still supported the complex patient bonus at the final score level (84 FR 40793 through 40795). More specifically, within the data analysis, we did not observe a consistent linear relationship for any reporting type or complexity measure, HCC risk score or dual proportion (84 FR 63021 through 63023). However, we only had a few years of data and believed more recent data may bring different results than the findings we explained in detail in the CY 2020 PFS final rule. We refer readers to the CY 2020 PFS final rule for further details on the methodology and findings (84 FR 63021 through 63023).

Further, section 1848(q)(1)(G) of the Act requires us to consider the relevant studies conducted under section 2(d) of the IMPACT Act and, as appropriate, other information, including information collected before completion of such studies and recommendations. The HHS Assistant Secretary for Planning and Evaluation (ASPE) completed its first report in December 2016, which examined the effect of individuals' socioeconomic status on quality, resource use, and other measures under the Medicare program, and included analyses of the effects of Medicare's current value-based payment programs on clinicians serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. ASPE's second report, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, was -released in June 2020, which builds on the analyses included in the initial report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs.[238] More specifically, the report has a 3-pronged strategy approach to: Measure and report quality; set high, fair quality standards; and reward and support better outcomes for beneficiaries with social risk. As a part of this 3-pronged strategy, the report supports use of the complex patient bonus in MIPS, explaining that it is well supported because this policy gives additional points to clinicians with a higher share of medically and socially complex patients and does not lower the standard of care. Further, the report suggested that we should not include the complex patient bonus within the final score that is publicly reported to ensure that patients can see the true clinician performance. Based on the ASPE report's suggestion, in the future we expect to also publicly report the final score without the complex patient bonus included. We noted in the CY 2021 PFS final rule (85 FR 84909) that as we continue to review the findings from the report, we intend to consider its recommendations, along with any updated data that would become available, for future rulemaking. In the CY 2021 PFS final rule (85 FR 84909), we also noted we plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries, and minimizing unintended consequences, and would propose modifications to the complex patient bonus in future rulemaking as appropriate.

Under § 414.1380(c)(3), the complex patient bonus is calculated as follows. For MIPS eligible clinicians and groups: [The average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5]. For APM entities and virtual groups: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the

[235] *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/forecasts-cases.html.*

[236] *https://www.nytimes.com/interactive/2021/us/covid-cases.html.*

[237] Ibid.

[238] ASPE. Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 29 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

APM entity or virtual group, respectively, × 5].

For this proposed rule, we continue to explore alternative calculation methodologies to modify the complex patient bonus formula based on several factors including stakeholder feedback, updated data analysis, and implications from ASPE reports to Congress. We also reviewed a series of literature recently published utilizing the 2017 MIPS performance period data. The Johnston KJ, Hockenberry JM et al. article [239] found that the current complex patient bonus formula appears unlikely to mitigate the most regressive effects of MIPS. The article stated this is particularly concerning for future years in MIPS as the performance threshold increases over time. Additionally, the Johnston KJ, Wiemken TL et al. article [240] indicated that lower composite MIPS scores in the higher-risk quintile reflected lower scores in each of the performance categories rather than one specific performance category. Essentially, both articles concluded that in the first year of the Medicare MIPS program, clinicians with the highest proportion of patients dually eligible for Medicare and Medicaid had significantly lower MIPS scores compared with clinicians with the lowest proportion of dually eligible patients. Two other research studies we considered are related to how risk scores, specifically related to HCCs, differ between both rural and urban areas. The Tyler Malone, Denise Kirk et al. study [241] indicated that Medicare beneficiaries in rural counties have lower average CMS–HCC risk scores compared to urban counties despite previous research suggesting that rural populations are sicker than urban populations. The study also emphasized the differences in average CMS–HCC risk scores may be driven partially by differences in the intensity of types of health care interventions received by rural versus urban beneficiaries. However, further research is needed to account for differences in coding patterns and/or resource limitations between urban versus rural counties. The second study [242] found CMS–HCC risk scores provide utility in predicting which patients are expected to be more costly. However, the results also suggested there are systematic differences in the risk adjustment model's predictive capabilities in rural versus urban populations, as rural beneficiaries in the Tyler Malone, Denise Kirk et al. study generally had greater health care utilization even after controlling for risk scores. In conclusion, both studies suggested Medicare provider payment models using CMS–HCC risks scores may underestimate the costs associated with treatment of rural beneficiaries.

While ASPE's reports to Congress support the use of a complex patient bonus at the final score level, we also acknowledge the findings reported in the published literature by identifying ways to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients and to mitigate differences in resources that affect MIPS scores. Once it became available, we reviewed the 2018 MIPS actual data to see if we could replicate the findings and identified some structural issues within the current complex patient bonus formula. We describe the findings below. We also note that the analyses reported in the Johnston KJ, Wiemken TL et al. studies include all MIPS eligible clinicians irrespective of whether they submitted data, while our data analyses with 2018 actual scored MIPS data were restricted to MIPS clinicians who submitted data. We restricted our analyses to MIPS eligible clinicians who submit MIPS data because under current policy as established at § 414.1380(c)(3), the MIPS eligible clinician must engage in, that is submit data for, at least one MIPS performance category for the applicable performance period for the MIPS payment year to receive the complex patient bonus. Our analysis of 2018 actual MIPS data was further limited to MIPS eligible clinicians scored as individuals or groups because the HCC and dual proportion individual data elements were not available for virtual groups and APM Entities at the time of our analysis.

For our updated analysis, we used actual 2018 MIPS scored data to evaluate whether the complex patient bonus sufficiently supports MIPS eligible clinicians scored as a group or individual who submit data and treat high risk and medically complex patients. We grouped the MIPS eligible clinicians into quintiles based on the complex patient bonus points they would receive. Quintiles were created by first ranking the actual complex patient bonus scores from lowest to highest for MIPS eligible clinicians who submitted data and were scored as an individual or group. All clinicians who received the same group score had the same complex patient bonus scores. Then, five groupings were created, each containing 20 percent of the MIPS eligible clinicians in our analysis. We found that MIPS final scores, prior to assigning the complex patient bonus points, were substantially lower for clinicians in the top two quintiles for the complex patient bonus compared to clinicians in the lower quintiles for the complex patient bonus when we refined the analysis by examining the HCC and dual proportion quintiles separately, we observed a similar pattern.

Currently, the complex patient bonus is awarded to all engaged clinicians, meaning those who have submitted data for at least one MIPS performance category or are facility-based, even clinicians serving beneficiaries with below-average dual proportion or HCC scores. Given our updated analysis showed that the MIPS performance of clinicians in the top two quintiles for each risk indicator, HCC and dual proportion, is substantially affected by the complexity of their patients among clinicians who submitted data and were scored as individuals and groups, we compared the respective contributions of the two risk indicators to the total points assigned. We found that approximately 55 percent of the points assigned are for the HCC risk indicator component and 45 percent for the dual proportion risk indicator component. However, we also observed that the additional points attributable to a one standard deviation increase in dual proportion were greater than those attributable to a similar increase in the HCC score.

In summary, our updated analyses using actual 2018 MIPS scored data found that clinicians who have a higher share of complex patients have lower final scores, on average, prior to the assignment of the complex patient bonus than other clinicians. Additionally, our analyses showed that there is little evidence of association between the complex patient risk indicators (HCC and dual proportion) and MIPS final scores among the clinicians with a lower share of complex patients. We also noted, based on the above analysis using actual 2018 MIPS

[239] Johnston KJ, Hockenberry JM et al (Sept 2020) ''Clinicians With High Socially At-Risk Caseloads Received Reduced Merit-Based Incentive Payment System Scores'' HEALTH AFFAIRS 39, NO. 9 (2020): 1504–1512. Khullar D, Schpero WL, et al (Sept 2020) ''Association between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System'' JAMA. 2020; 324 (10):975–983.

[240] Johnston KJ, Wiemken TL et al (Sept 2020) ''Association of Clinician Health System Affiliation with Outpatient Performance Ratings in the Medicare Merit-based Incentive Payment System'' JAMA. 2020; 324(10):984–992.

[241] UNC Rural Health Research Program, ''CMS Hierarchical Condition Category (HCC) 2014 Risk Scores Are Lower for Rural Medicare Beneficiaries than for Urban Beneficiaries,'' December 2020.

[242] UNC Rural Health Research Program, ''Association of CMS-HCC Risk Scores with Health Care Utilization Among Rural and Urban Medicare Beneficiaries'', December 2020.

scored data for clinicians scored as individuals and groups examined separately, the median raw final scores for engaged clinicians in the calculated top complex patient bonus quintile were more than 10 points less than the median raw final score of those in the bottom complex patient bonus quintile. Specifically, the median raw final scores for engaged clinicians in the top complex patient bonus quintile were 82.33 for groups and 60.76 for individuals compared to median raw scores of 94.36 for groups and 81.28 for individuals in the lowest quintile. Additionally, when we compared the median raw final scores for engaged clinicians in the calculated middle complex patient bonus quintile to the highest quintile, we still observed a difference in median raw final scores of greater than 10 points for both individuals and groups. Table 49 shows 2018 median MIPS raw final scores for the engaged individuals and groups within the lowest, middle and highest complex patient bonus (CPB) quintiles.

TABLE 49: 2018 Median MIPS Raw Final Scores for Engaged Individuals and Groups by Complex Patient Bonus Quintile

	Lowest CPB Quintile	Middle CPB Quintile	Highest CPB Quintile
Median MIPS Final Score (Individual)	81.28	77.44	60.76
Median MIPS Final Score (Group)	94.36	94.38	82.33

Furthermore, we found that, while the two risk indictors, dual proportion and HCC risk score, are correlated substantially, each has a different scale. For example, the dual proportion has a natural upper bound of 1 whereas the HCC risk score does not. The distribution of each risk indicator around its mean and median is also different. Given these findings, we have identified areas within the complex patient bonus that can be improved. Most importantly, the current complex patient bonus formula gives bonus points to clinicians not adversely affected by social risk and medical risk of their patients and does not sufficiently account for clinicians who treat patients who are high-risk and/or medically complex.

(B) Proposed Updates to the Complex Patient Bonus Beginning With the CY 2022 MIPS Performance Period/CY 2024 MIPS Payment Year

Based on the ASPE report and our analyses, we are proposing to revise the complex patient bonus by—(1) limiting the bonus to clinicians who have a median or higher value for at least one of the two risk indicators (HCC and dual proportion); (2) standardizing the distribution of the two risk indicators so that the policy can target clinicians who have a higher share of socially and/or medically complex patients; and (3) providing one overall complex patient bonus cap at 10 bonus points. To accomplish this, we include five separate proposals to update our complex patient bonus for the CY 2022 MIPS performance period/CY 2024 MIPS payment years and future MIPS performance periods/MIPS payment years. We note that in section IV.A.3.e.(2)(a)(iii)(B) of this proposed rule, we use the term ''clinician(s)'' to generally refer to those individuals and entities that these proposals apply to, including MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups. First, we propose to add to § 414.1380(c)(3) that, similar to our current policy, beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraph (c)(3)(v) through (c)(3)(viii). Second, we propose at § 414.1380(c)(3)(v) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. Third, we propose the revised formulas at § 414.1380(c)(3)(vi). For MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: medical complex patient bonus component = 1.5 + 4*associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component =1.5 + 4* associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. Fourth, we propose the revised formulas at § 414.1380(c)(3)(vii). For APM entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: medical complex patient bonus component = 1.5 + 4* the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4* the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. Finally, we propose at § 414.1380(c)(3)(viii) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years,

the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

(aa) Continuing the Requirement To Submit Data and To Use the Same Risk Indicators

Under the first proposal, beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years, we are proposing to continue the requirement to submit data for at least one MIPS performance category for the applicable performance period for the MIPS payment year for a MIPS eligible clinician, group, subgroup, virtual group or APM entity to receive a complex patient bonus added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii).

As discussed below in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this proposed rule, the proposals at § 414.1380(c)(3)(vi) and (vii) include complex patient bonus components within the formulas proposed beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year to account for social and medical risk, while still using our current established risk indicators of dual proportion and HCC risk scores, respectively. We also continue to believe that applying this bonus at the final score is appropriate because caring for complex and vulnerable patients can affect all aspects of a practice and not just specific performance categories.

(bb) Cutoff at the Median for Complex Patient Bonus Beginning With the CY 2022 MIPS Performance Period/CY 2024 MIPS Payment Year

Beginning with the CY 2018 MIPS performance period/CY 2020 MIPS payment year, a complex patient bonus was added to the final score for the MIPS payment year for all MIPS eligible clinicians, groups, virtual groups and APM entities if they submitted data for at least one MIPS performance category for the applicable performance period for the MIPS payment year (§ 414.1380(c)(3)). We did not include any requirement that clinicians had to attain a certain threshold to receive the complex patient bonus. Under the second proposal, we are proposing at § 414.1380(c)(3)(v), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median. This proposal limits the component for social risk to clinicians with a dual proportion value at or above the median dual proportion, and it limits the component for medical risk to clinicians with an HCC score value at or above the median HCC score. Those at or above the median for a risk indicator will get complex bonus points for that risk indicator component. To ensure the points are impactful and provided specifically to clinicians treating higher numbers of medically and socially complex patients, we propose to provide bonus points beginning at the respective calculated medians.

Both medical and social factors within the newly proposed methodology, discussed in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this proposed rule, would have separate medians and distributions calculated to provide more transparent bonuses to directly target those clinicians who treat a higher caseload of high-risk and complex patients. Both the dual proportion and the HCC risk indicators attributed to each clinician will be calculated in the same manner as under our current policy (for more information about the current policy, see the CY 2018 Quality Payment Program final rule (82 FR 30135)).

To determine the median for the respective risk indicator (HCC and dual proportion), we propose to use the risk indicators associated with the final score assigned to a clinician from the prior performance period for all engaged MIPS clinicians, which means those who have submitted data for at least one MIPS performance category or are facility-based. We would also use this same final score distribution to determine the standardized score discussed in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this proposed rule. These statistics would be applied to the applicable performance period values of the risk indicators for each clinician to calculate the social and medical risk component scores for the MIPS performance period. For example, the median from the CY 2021 performance period would be compared to the CY 2022 MIPS performance period risk indicator values to determine who would be eligible for a CY 2022 MIPS performance period/CY 2024 MIPS payment year complex patient bonus. We believe we need a prospective determination of the median, and standardized score from a prior performance period where the final scores are already resolved.

In our proposal, only those clinicians with risk indicator scores at or above the median for either one or both risk indicators would receive complex patient bonus points. Based on this proposed rule's regulatory impact analysis (see section VII.F.17 of this proposed rule), we estimate 64 percent of clinicians would receive a complex patient bonus because there is not 100 percent overlap in the clinicians that are at or above the median for both risk indicators. Approximately 36.3 percent of engaged clinicians would not receive any complex patient bonus points, as they are below the median for both the HCC risk score and the dual proportion. We believe this number is appropriate as we would be targeting the complex patient bonus points to clinicians treating a higher caseload of highly complex patients.

Additionally, the complex patient bonus points would be more impactful as the difference in awarded bonus points between those with high caseloads of complex patients and those with low caseloads, would be greater. We believe establishing a cutoff point at the median, as opposed to the mean, is appropriate given the median is less impacted by outlier cases since the median is simply the middle value. We considered whether to use the mean, instead of the proposed median, but estimated that would result in about 50 percent of clinicians no longer receiving any complex patient bonus points because outliers could increase the mean.

We acknowledge that alternate approaches could be used to target the bonus at clinicians with higher caseloads of complex patients. For example, we could consider using a different distribution of risk indicator scores, such as one from an earlier performance period, so clinicians could know their scores in advance, or through using a distribution that includes individual clinician scores and counts group scores, APM Entity scores, virtual group scores, and, starting in the CY 2023 MIPS performance period/CY 2025 MIPS payment year, subgroup scores only once, so the group, APM Entity, virtual group, or subgroup score is not weighted by the number of clinicians in the group, APM Entity, virtual group, or subgroup. We could also consider building risk benchmarks based on our current quality measure benchmark methodology (81 FR 77282 and 82 FR 53718) to determine the number of complex patient bonus points. Under that methodology, risk indicator scores higher than the decile in which the median risk factor lies would receive complex patient bonus points and all of the clinicians in the top decile would receive 5 points for each risk indicator. We request comments on alternate approaches for calculating the complex patient bonus.

(cc) Revised Complex Patient Bonus Formulas Beginning With the CY 2022 MIPS Performance Period/CY 2024 MIPS Payment Year

Under the third proposal, we propose at § 414.1380(c)(3)(vi) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment, for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4* associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS under section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5 + 4* associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation. For example, we would use the mean and standard deviation from the CY 2021 MIPS performance period and the indicator assigned in the CY 2022 MIPS performance period to determine the clinician's standard score for the CY 2022 MIPS performance period/CY 2024 MIPS payment year.

Under the fourth proposal, we also propose at § 414.1380(c)(3)(vii), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment years, for APM entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4* the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4* the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

The mean and standard deviation statistics will be used along with the performance period values of the risk indicators for each clinician to calculate the standardized score used to calculate the social and medical risk component scores for the MIPS payment year. For example, if the raw dual proportion score calculated for a clinician is 0.25, the dual proportion mean (from the prior performance period) is 0.23, and the dual proportion standard deviation (from the prior performance period) is 0.15, the clinician's standardized score would be (0.25 − 0.23)/0.15 = 0.13. We believe that the standardized score calculation is appropriate as it is typically used to understand how far the raw risk indicator scores fall from the mean. We note that those with a mean score would have a standardized score of zero, and those with a standardized score of 1 are one standard deviation above the mean. Those below the mean would have a negative standardized score. The proposed formulas would also provide bonus points to clinicians who have a negative risk indicator standardized score and fall between the calculated median and mean for the respective risk indicator and to those who fall at or above the mean and thus have a positive risk indicator standardized score. As noted in section IV.A.3.e.(2)(a)(iii)(B)(cc) of the proposed rule, at § 414.1380(c)(3)(vi) and (vii), the new bonus components would use respective means to calculate standardized scores to then calculate and provide bonus points for clinicians with risk indicators, HCC and dual proportion, at or above the median, to capture medical and social risk, separately. For each of the two component calculations, higher standardized scores above the mean would be associated with more bonus points. For example, a clinician with a standardized score of zero (the mean value) for each risk indicator, HCC and dual proportion, would receive bonus points for each component that is equivalent to the constant, additive factor within the new formula, 1.5. The proposed formulas acknowledge complexity without creating a large cliff between those who are just below the median and those who have a marginally higher caseload of complex patients. The bonus, as proposed, would increase proportionally with the increased number of complex patients a clinician is treating and/or the degree of patient complexity. For example, we would not want to provide those who fall at the mean 1.5 bonus points, and then provide 10 bonus points to those who only have only a slightly higher caseload. Hence, we intend to incorporate a standardized score multiplied by 4 to ensure the score gets proportionally higher as complexity increases.

The additive factor of 1.5 ensures that all clinicians at or above the mean for the social complex patient bonus calculation, based on dual proportion, would receive at least 1.5 complex patient bonus points and all clinicians at or above the mean for the medical complex patient bonus calculation, based on HCC risk score, would receive at least 1.5 complex patient bonus points. Further, the additive factor of 1.5 would allow clinicians between the median and mean to still receive complex patient bonus points. For example, if the dual proportion risk indicator median is 0.2 and the dual proportion risk indicator mean is 0.23, a clinician with an associated standardized score of −0.1 (0.1 standard deviations below the mean, but still above the median), the clinician would receive a complex patient bonus equal to 1.5 + 4 * (−0.1) which equals 1.1 for the dual proportion component. If the dual proportion risk indicator calculated for a clinician falls below the median, they would receive zero complex patient bonus points for the dual proportion component. Based on the standardized score calculation, if the dual proportion risk indicator calculated for a clinician falls above the mean, they would receive complex patient bonus component points greater than the additive factor of 1.5 for the dual proportion component.

We believe this formula avoids a major complex patient bonus points cliff created by providing the clinicians right *above* the cutoff point significant bonus points compared to the clinicians right *below* the cutoff point (who do not receive any complex patient bonus points). We acknowledge those who fall below the median will no longer receive any complex patient bonus points, per proposal at § 414.1380(c)(3)(v) that for the CY 2022 MIPS performance period/CY 2024 MIPS payment years and future MIPS performance periods/MIPS payment years, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk

indicator at or above the risk indicator calculated median.

(dd) Cap for the Complex Patient Bonus Beginning With the CY 2022 MIPS Performance Period/CY 2024 MIPS Payment Year

When we originally established the complex patient bonus policy in the CY 2018 Quality Payment Program final rule (82 FR 53774), we finalized at § 414.1380(c)(3)(iii) that the complex patient bonus cannot exceed 5.0. At that time, our data analysis estimated a decrease in simulated scores of 5.4 points (for individuals who report 6 or more quality measures) and 4.5 points (for groups) from the top quartile to the bottom quartile for the average patient HCC risk scores and 4.8 points (for individuals who report 6 or more quality measures) and 4.5 points (for groups) from the top quartile to the bottom quartile for the dual proportion. Therefore, we believed a cap for the complex patient bonus of 5 points was supported by the data and was sufficient to compensate for the estimated differences in performance based on HCC risk scores and dual proportion (82 FR 53773). In CY 2019, CY 2020, and CY 2021 PFS final rules, we continued to believe that the 5-point cap was appropriate given that we had not updated our prior analyses (83 FR 58769 through 59870, 84 FR 63021 through 63023, 85 FR 84908 through 84913, respectively). However, based on our updated analyses using actual 2018 MIPS scored data, described above, about 5 percent of clinicians scored as group or individual had a complex patient bonus that would have been more than 5-points had the cap not been in place. The complex patient bonus cap of 5-points (82 FR 53773 through 53776) affects clinicians who are most likely carrying higher caseloads for patient complexity, which is inconsistent with the intent of the policy, and we no longer believe we should maintain the overall cap of 5-points. As discussed in section IV.A.3.e.(2)(a)(iii)(A), our updated analyses using actual 2018 MIPS scored data also found that clinicians with a higher caseload of complex patients have lower final scores, by more than 10 points on average, prior to the assignment of the complex patient bonus than clinicians with lower caseloads of complex patients. We believe, with a cap of 10 bonus points, we are targeting the bonus to address the differences in final scores these clinicians face more appropriately without capping at a larger number, such as 15 or 20 bonus points, which could result in inappropriate score inflation and masking of poor performance. A cap of fewer than 10 bonus points would not address the differences in the observed raw final scores and would not adequately address the need to provide more equity within our scoring system for those clinicians treating higher caseloads of socially and/or medically complex patients. We did consider lower caps, such as 5 or 7 bonus points, or higher caps, such as 20 bonus points, but, for the reasons described above, have proposed the cap of 10 bonus points. However, if future analyses and more recent data show differences in raw final scores that differ from our previous findings, we would consider proposing in future rulemaking the use of a cap that aligns with new findings.

As discussed in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this proposed rule, we are proposing the formulas as: risk indicator complex patient bonus component = 1.5 + 4* associated risk indicator standardized score. The formula, as proposed, has a multiplier of 4. We also considered a multiplier of 2 with a cap of 5 bonus points which results in a lower final score mean and median but does not change the number of clinicians receiving a complex patient bonus when compared to the proposed policy. We do not believe that this alternate approach would produce a bonus impactful enough to overcome the differences seen at the final score level when comparing complex patient bonus quintiles. We request feedback on this alternate approach and additional alternate approaches we should consider.

Under the fifth proposal, we are proposing at § 414.1380(c)(3)(viii) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0. Based on the proposed formulas at § 414.1380(c)(3)(vi) and (vii), the social complex patient bonus component (using dual proportion standardized score) and the medical complex patient bonus component (using HCC risk score standardized score) will be added together to calculate one overall complex patient bonus. Then, based on the proposal at § 414.1380(c)(3)(viii) the complex patient bonus would then be capped at the 10 points overall. The benefit would be targeted toward those clinicians treating medically and socially complex patients.

For example, if a clinician's dual proportion standardized score is 1.5, their complex patient bonus social risk component is 1.5 + 4 * 1.25 = 6.5. If their HCC risk score standardized score is 0.25, their complex patient bonus medical risk component is 1.5 + 4 * 0.25 = 2.5. The two complex patient bonus components are then added together to total 9 complex patient bonus points for this clinician. Had the total been above 10 bonus points, the 10-point cap would have applied and the clinician would have received 10 complex patient bonus points added to their final MIPS score.

We seek feedback on whether we should use the multiplier of 4 and cap of 10 bonus points as proposed, a multiplier of 2 and cap of 5 bonus points as discussed as an alternative, or if we should consider additional options and rationale for the complex patient bonus formula and bonus cap, such as a cap of 7 or 20 bonus points.

In summary, we propose the five separate proposals for the CY 2022 MIPS performance period/CY 2024 MIPS payment year and future MIPS performance periods/MIPS payment years as follows:

- To revise § 414.1380(c)(3), by adding, beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (viii).
- At § 414.1380(c)(3)(v), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we propose the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median.
- At § 414.1380(c)(3)(vi), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we proposed for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (under the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroups; social complex patient bonus component = 1.5 + 4 * associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each

risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

- At § 414.1380(c)(3)(vii), we propose that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, for APM entities and virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5 + 4 * the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM entity or virtual group, respectively; social complex patient bonus component = 1.5 + 4 * the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.
- At § 414.1380(c)(3)(viii), beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we propose the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

We seek comments on these proposals including the different aspects of the updated complex patient bonus formulas, such as the additive and multiplicative components, the cutoff point (the median), and the 10-point overall cap. For all of the reasons described above in sections IV.A.3.e.(2)(a)(iii), IV.A.3.e.(2)(a)(iii)(A) and (B), and IV.A.3.e.(2)(a)(iii)(B)(aa) through (dd) of this rule, we have proposed such policies. However, we did also consider the alternative of continuing the use of the complex patient bonus formulas, as previously finalized at § 414.1380(c)(3)(i) and (ii), along with the 5.0 point cap as previously finalized at § 414.1380(c)(3)(iii) for the CY 2022 MIPS performance period/CY 2024 MIPS payment year. We also seek comment on that alternative.

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2021 PFS final rules (81 FR 77320 through 77329, 82 FR 53779 through 53785, 83 FR 59870 through 59878, and 84 FR 62950 through 62959, 85 FR 84898 through 84908, respectively). Table 50 summarizes the weights established in prior rulemaking (85 FR 84913) for each performance category for the CY 2022 MIPS performance period/CY 2024 MIPS payment year and each subsequent MIPS payment year.

TABLE 50: Weights by MIPS Performance Category for the CY 2022 MIPS Performance Period/CY 2024 and each Subsequent MIPS Payment Year

Performance Category	2024 and Future MIPS Payment Years
Quality	30%
Cost	30%
Improvement Activities	15%
Promoting Interoperability	25%

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved.

Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician generally would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Under certain circumstances, however, a MIPS eligible clinician who fails to report could be eligible for an assigned scoring weight of zero percent and a redistribution of the performance category weights. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2021 PFS final rule (85 FR 84914 through 84916).

(A) Reweighting the Cost Performance Category

Under § 414.1380(c)(2)(i)(A), we will assign a different weight to a performance category and redistribute its prescribed weight to another performance category or categories in certain circumstances where we determine there are not sufficient measures and activities applicable and available under section 1848(q)(5)(F) of the Act. For the cost performance category, this includes circumstances where we cannot reliably calculate a score for the cost measures which adequately captures and reflects the performance of a MIPS eligible clinician (*see* § 414.1380(c)(2)(i)(A)(2)). In the CY 2018 Quality Payment Program final rule (82 FR 53780), for the cost performance category, we noted in the

proposed rule we had stated that we continue to believe having sufficient measures applicable and available means that we can reliably calculate a score for the cost measures which adequately captures and reflects the performance of a MIPS eligible clinician, and that MIPS eligible clinicians who are not attributed enough cases to be reliably measured should not be scored for the cost performance category. We noted (82 FR 53780) we had established a policy in the CY 2017 Quality Payment Program final rule that if a MIPS eligible clinician is not attributed enough cases for a measure (in other words, has not met the required case minimum for the measure), or if a measure does not have a benchmark, then the measure will not be scored for that clinician (81 FR 77323). We stated (82 FR 53780) if we do not score any cost measures for a MIPS eligible clinician in accordance with this policy, then the clinician would not receive a cost performance category percent score. In this section of the proposed rule, we are requesting comments on potential circumstances where we may not be able to reliably calculate a score for any of the cost measures which adequately captures and reflects the performance of a MIPS eligible clinician, and may assign a different weight to the cost performance category and redistribute its prescribed weight to another performance category or categories. We are interested in comments on circumstances that could affect all MIPS eligible clinicians, as well as those that could affect a subset of MIPS eligible clinicians or individual MIPS eligible clinicians. The cost performance category reweighting provision at § 414.1380(c)(2)(i)(A)(*2*) is distinct from the measure suppression policy proposed in section IV.A.3.e.(1)(d)(i) of this proposed rule, as it applies to the performance category as a whole and not on a measure-by-measure basis.

In the CY 2021 PFS final rule (85 FR 84880), we responded to commenters' concerns regarding the potential for COVID–19 to impact cost measures, noting various features of the cost measures could allow us to calculate cost measures without penalizing practices in COVID–19 hotspots, and policies were in place to account for circumstances when a cost measure cannot be reliably calculated to adequately capture and reflect clinician performance. First, we noted service assignment allows the episode-based measures to capture the cost of services clinically related to the triggering event for the episode, reducing the likelihood of the measures to capture costs resulting from high volumes of COVID–19 treatment services. Then, we noted the measures are adjusted for clinical risk to account for different levels of care beneficiaries may require due to comorbidities, disability, age, and other risk factors (including clinical characteristics based on the beneficiary's recent medical history) to ensure attributed clinicians are not penalized for factors beyond their influence. Finally, we noted the cost measures use standardized claims to account for differences in Medicare payments for the same services across health care providers, removing the effect of regional differences in health care costs and the payment standardization process removes the 20 percent increase in the IPPS relative weight under the CARES Act for individuals diagnosed with COVID–19.

After the publication of the CY 2021 PFS final rule, we continued to monitor the cost measures to determine whether we could reliably calculate the cost measures for the 2020 performance period. Due to the claims run-out period, there is an inherent delay between the time at which we can observe trends in claims and when we can test for potential impact on cost measures, to ensure that the data included in our analyses reflect final claims for all services in episodes. In addition, a drop-in service utilization early in 2020 would only affect the amount of information available to risk adjust for patient clinical factors for episodes beginning in the second half of the year as the episode-based measures use a 120-day look back period during which we look for HCC indicators. When considering these factors, along with the length of the episode windows for the measures and the need to include as many episodes in our study as possible, we had to complete our monitoring and assessment after the end of the CY 2020 MIPS performance period.

Based on our analyses using the full year of data from 2020, we considered many factors and concluded we cannot reliably calculate scores for the cost measures that adequately capture and reflect clinician performance due to the unique changes to healthcare in the COVID–19 pandemic. Our analyses showed substantial decreases in service utilization in 2020 compared to 2019 across all care settings. This can affect risk adjustment and the ability to adequately reflect clinician performance on cost measures. Since we look for diagnosis information in a beneficiary's claims history during a lookback period before the start of the episode to capture HCC indicators and other clinical risk factors used in risk adjustment, a decrease in service utilization means that there are fewer claims from which we can identify risk adjustors. There was a systematic decrease in the ratio of the number of HCCs identified for risk adjustment in 2020 compared to 2019 in the second half of the year across all the measures. We note this finding coincides with when we observed the steepest drops in service utilization due to the length of the lookback period. There was also a systematic decrease in the ratio of the number of episodes in 2020 compared to 2019. This indicates the overall decrease in service utilization is indeed reflected in fewer episodes being triggered and demonstrates the wide-ranging impact of COVID–19 across the range of care that the cost measures capture. Separately from the decrease in service utilization, our analyses demonstrate that episodes with COVID–19 diagnoses generally have higher observed, payment-standardized costs than episodes without COVID–19 diagnoses. These differences are also present when comparing risk-adjusted costs for episodes with and without COVID–19 diagnoses. This shows despite service assignment rules for episode-based measures, beneficiaries diagnosed with COVID–19 had higher payment-standardized costs of care which was not sufficiently accounted for through risk adjustment or other features of cost measures.

Because we determined we cannot reliably calculate scores for the cost measures that adequately capture and reflect the performance of MIPS eligible clinicians, we announced via email communication (*subject: CMS Reweighting 2020 MIPS Cost Performance Category*) on May 20, 2021, in accordance with § 414.1380(c)(2)(i)(A)(*2*), we will assign a weight of 0 percent to the cost performance category for the CY 2020 MIPS performance period/CY 2022 payment year and redistribute the prescribed weight of 15 percent to another performance category or categories, as established at § 414.1380(c)(2)(ii)(D). We note as with all measures, we continue to monitor the evolving impact of COVID–19.

We recognize there may be additional circumstances where we may not be able to reliably calculate a score for any of the cost measures within the cost performance category that adequately captures and reflects the performance of a MIPS eligible clinician, which could include external factors beyond the control of clinicians. Similar to the Measure Suppression Factors discussed

in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25473), such external factors may include significant national shortages or rapid or unprecedented changes in: (1) Healthcare personnel; (2) medical supplies, equipment, or diagnostic tools or materials; or (3) patient case volumes or patient case mix. We request comment on whether these external factors should inform our future decision-making on whether to reweight the cost performance category under § 414.1380(c)(2)(i)(A)(*2*). We also request comment on whether there are other external factors we should consider, or other circumstances in general that could affect our ability to reliably calculate a score for the cost performance category as described under § 414.1380(c)(2)(i)(A)(*2*).

(iii) Redistributing Performance Category Weights

In the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2021 PFS final rules (81 FR 77325 through 77329, 82 FR 53783 through 53785, 83 FR 59876 through 59878, 84 FR 63027 through 63031, and 85 FR 84914 through 84916), and at § 414.1380(c)(2)(ii), we established policies for redistributing the weights of the performance categories in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories.

In CY 2021 PFS final rule, we finalized a policy for redistributing the performance category weights for the CY 2022 MIPS performance period/CY 2024 MIPS payment year and noted that we planned to revisit our redistribution policies in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent (85 FR 84914). While we still intend to redistribute more weight to the cost performance category in future years, we believe it would be beneficial to establish the redistribution policies for the CY 2023 MIPS performance period/CY 2025 MIPS payment year and future years to provide as much notice as possible to clinicians and other stakeholders. Hence, we propose to apply the redistribution policy finalized for the 2022 MIPS performance period/2024 MIPS payment year at § 414.1380(c)(2)(ii)(F) to the 2025 MIPS payment year and each subsequent MIPS payment year, and we propose corresponding revisions to § 414.1380(c)(2)(ii)(F). We still plan to revisit our redistribution policies in future rulemaking after clinicians have more experience with cost being weighted at 30 percent and gain more experience with our newly proposed MVPs. Our proposed redistribution policies for the 2025 MIPS payment year and each subsequent MIPS payment year are included in Table 51. We note that not all the redistribution scenarios described in Table 51 would apply to MIPS eligible clinicians in small practices, so we also propose at § 414.1380(c)(2)(ii)(F) an exception for a new paragraph (G) which applies to small practices. Please refer to Table 52 for the proposed redistribution policy for small practices.

We request public comment on this proposal.

TABLE 51: Performance Category Redistribution Policies Finalized for the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Proposed for Future MIPS Performance Periods/MIPS Payment Years

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	55%	30%	15%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

(A) Redistributing Performance Category Weight for Small Practices

Clinicians and groups who work in small practices are a crucial part of the health care system. The Quality Payment Program provides options designed to make it easier for these clinicians and groups to report on performance and quality and participate in advanced alternative payment models for incentives. We have heard directly from clinicians in small practices that they face unique challenges related to financial and other resources, environmental factors, and access to health information technology. We heard from many commenters that the Quality Payment Program gives an advantage to large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS (82 FR 53776). In response to the feedback on the potential burden on small practices, we have established special policies available for small practices including the small practice bonus and special scoring policies. For example, in the CY 2018 QPP final rule (82 FR 53682 through 53683), we established a significant hardship exception for small practices for the

Promoting Interoperability performance category.

In this section of the proposed rule, we discuss how we would redistribute the Promoting Interoperability performance category weight for small practices. Within the reweighting policy for the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the Promoting Interoperability performance category weight is redistributed fully to the quality performance category, unless the quality performance category is weighted at zero percent. In general, our reweighting policies have emphasized the quality performance category over the improvement activities performance category. We have noted it is important to prioritize performance on measures that show a variation in performance such as quality measures, rather than the activities under the improvement activities performance category, which are based on attestation of completion (85 FR 84914). We believe this helps reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. However, given stakeholder input and recently published literature, we believe there could be other reasons why a small practice would not report quality measures. One recent article [243] stated that physicians in larger group practices, multispecialty practices, or participating through alternative payment models had higher MIPS scores, possibly reflecting such practices' greater infrastructure and resources to collect, analyze, and report measures to CMS. We have also heard directly from clinicians in small practices that they face unique challenges related to financial and other resources and access to health information technology. Many commenters have shared their belief that the Quality Payment Program gives an advantage to large organizations because such organizations have more resources invested in the infrastructure required to track and report measures to MIPS (82 FR 53776). Indeed, 85 percent of clinicians who are not engaged with MIPS (who do not submit data) are clinicians in small practices (85 FR 85018), which we believe may be due to their limited resources. Given infrastructure and resource limitations within small practices, we believe it is appropriate to place more emphasis on a performance category that poses a reduced reporting burden such as the improvement activities performance category. We propose that for small practices, as defined at § 414.1305, when the Promoting Interoperability performance category is reweighted, the quality performance category will be weighted at 40 percent, the cost performance category will be weighted at 30 percent, and the improvement activities performance category will be weighted at 30 percent. When both the cost performance category and the Promoting Interoperability performance category are reweighted, the quality performance category will be weighted at 50 percent and the improvement activities performance category will be weighted at 50 percent. We plan to revisit this redistribution policy in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent.

We anticipate that our proposal noted in the two rows in Table 52 will greatly assist small practices by providing further flexibilities to help with our goal of increasing engagement across the MIPS program and to be able to meet the MIPS requirements. Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, we propose at § 414.1380(c)(2)(ii)(G) redistribution policies for small practices, as shown in Table 52.

We request public comment on this proposal.

TABLE 52: Performance Category Redistribution Policies for Small Practices Proposed for the CY 2022 MIPS Performance Period/CY 2024 MIPS Payment Year and Future MIPS Performance Periods/MIPS Payment Years

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability*	40%	30%	30%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability*	50%	0%	50%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

*the proposed redistribution policy specifically for MIPS eligible clinicians in small practices.

[243] Johnston KJ, Wiemken TL et al. (Sept 2020) ''Association of Clinician Health System Affiliation with Outpatient Performance Ratings in the Medicare Merit-based Incentive Payment System'' JAMA. 2020; 324(10):984–992.

(iv) MIPS Reweighting Based on Extreme and Uncontrollable Circumstances

(A) MIPS Applications for Reweighting for the CY 2021 MIPS Performance Period/CY 2023 MIPS Payment Year Based on Extreme and Uncontrollable Circumstances

We anticipate that the national PHE for COVID–19 will continue through CY 2021. Therefore, we remind clinicians that the application-based extreme and uncontrollable circumstances policy, as described in § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*), will be available for the CY 2021 performance period/CY 2023 MIPS payment year (85 FR 84916 through 84917). Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for details. The application allows clinicians, groups, and virtual groups significantly impacted by the PHE for COVID–19 to request reweighting for any or all MIPS performance categories. Under this policy, if a clinician, group, or virtual group submits a reweighting application and also submits data for a performance category for which an application was submitted, the data submission will override the application, and the clinician, group, or virtual group will be scored on the data submitted.

Additionally, if an application is submitted for one performance category only, and data is submitted for the other 2 performance categories, only the performance category for which the application was submitted will be reweighted and the other performance categories will be scored. We believe this approach maintains a balance of encouraging participation in the Quality Payment Program while still providing for flexibility in weighting the performance categories for those who have been affected by the national PHE for COVID–19. Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for more information.

(B) MIPS Reweighting Based on Extreme and Uncontrollable Circumstances; Automatic and Application-Based Policies Clarification

Under the application-based extreme and uncontrollable circumstances policy codified at § 414.1380(c)(2)(i)(A)(*6*) for the quality, cost, and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(*2*) for the promoting interoperability performance category, clinicians who are subject to extreme and uncontrollable circumstances may submit an application to CMS to request reweighting of a performance category or categories. We also established an automatic extreme and uncontrollable circumstances policy at § 414.1380(c)(2)(i)(A)(*8*) for the quality, cost, and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(*3*) for the promoting interoperability performance category, under which we automatically reweight the performance categories for clinicians who are located in an area affected by extreme and uncontrollable circumstances as identified by us.

Based on stakeholder inquiries, we recognize not all stakeholders understand how individual MIPS eligible clinicians who are eligible for reweighting under the automatic extreme and uncontrollable circumstances policy and who also submit an application for reweighting based on extreme and uncontrollable circumstances are affected by the intersection of these policies. Currently, under both the application-based and automatic extreme and uncontrollable circumstances policies, if a MIPS eligible clinician who is located in an area affected by extreme and uncontrollable circumstances as identified by CMS submits data for any of the MIPS performance categories by the applicable submission deadline for the MIPS performance period, they will be scored on each performance category for which they submit data, and the performance category will not be reweighted to zero percent in the final score. Under the automatic extreme and uncontrollable circumstances policy, the other performance categories for which data was not submitted will remain reweighted to zero percent (82 FR 53898, 83 FR 59874). Additionally, as described in the CY 2019 PFS final rule (83 FR 59874), under the automatic extreme and uncontrollable circumstances policy, a MIPS eligible clinician who is located in an area affected by extreme and uncontrollable circumstances as identified by CMS will not be scored on the cost performance category. As we stated in the CY 2019 PFS final rule (83 FR 59874), if a MIPS eligible clinician is located in an affected area, we would assume the clinician does not have sufficient cost measures applicable to him or her and assign a weight of zero percent to that category in the final score, even if we receive administrative claims data that would enable us to calculate the cost measures for that clinician.

The following example is intended to illustrate the intersection of the automatic and application-based extreme and uncontrollable circumstances policies. A MIPS eligible clinician who is located in an area affected by extreme and uncontrollable circumstances as identified by CMS and eligible for the automatic extreme and uncontrollable circumstances policy submits an application for reweighting based on extreme and uncontrollable circumstances. The application requests reweighting for the Promoting Interoperability performance category, and the clinician submits data for the quality and improvement activities performance categories. The clinician will be scored on the quality and improvement activities performance categories because they submitted data for those categories; the cost performance category is reweighted to zero percent under the automatic extreme and uncontrollable circumstances policy, as discussed above; and the Promoting Interoperability performance category is also reweighted to zero percent under the automatic extreme and uncontrollable circumstances policy. The application for reweighting was not needed in this example to reweight the Promoting Interoperability performance category.

Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for more information.

(v) Redistributing Performance Category Weights for Facility-Based Measurement

(A) Background

In the CY 2018 Quality Payment Program final rule, we established facility-based measurement under section 1848(q)(2)(C)(ii) of the Act which provides that the Secretary may use measures used for payment systems other than for physicians, such as measures for inpatient hospitals, for purposes of the quality and cost performance categories (82 FR 53752 through 53767). Scoring under facility-based measurement was available for clinicians beginning with the CY 2019 MIPS performance period/CY 2021 MIPS payment year. We established facility-based measurement to better align incentives between facilities and the MIPS eligible clinicians who provide services there (82 FR 53753). For more background on facility-based measurement, we refer readers to both the CY 2018 Quality Payment Program final rule (82 FR 53752 through 53767) and the CY 2019 PFS final rule (83 FR 59856 through 59867).

(B) Redistribution of Performance Category Weights Under Facility-Based Measurement

In the CY 2019 PFS final rule, we established that clinicians and groups would not need to elect or opt-in to

facility-based measurement, but instead we would automatically apply facility-based measurement to MIPS eligible clinicians and groups who are eligible for facility-based measurement and who would benefit by having a higher combined quality and cost performance category score (83 FR 59863). In this same final rule, we finalized policies for redistributing weight among the performance categories for the 2019 MIPS performance period/2021 MIPS payment year under § 414.1380(c)(2)(ii)(C). Under those redistribution policies, if the cost performance category is reweighted to zero percent of the final score, its weight is redistributed entirely to the quality performance category, unless the quality performance category is reweighted to zero percent, in which case the quality and cost performance category weights would be redistributed to the improvement activities and Promoting Interoperability performance categories. A clinician or group could have the weight of the cost performance category redistributed because they did not meet the case minimum for any of the measures in the cost performance category. Because facility-based measurement always includes both the quality and cost performance categories, it is possible a clinician or group would be scored on the cost performance category under facility-based measurement but not outside of facility-based measurement. There are two common scenarios for a facility-based clinician or group which could occur in the 2019 MIPS performance period/2021 MIPS payment year. In the first scenario, a facility-based clinician or group meets the case minimum for at least one cost performance category measure and receives a cost performance category percent score as defined at § 414.1380(b)(2). The respective quality and cost scores would be multiplied by the available points in the quality performance category (45 points) and the available points in the cost performance category (15 points) to determine the combined contribution of the quality performance category and the cost performance category to the final score out of the available 60 points. In the second scenario, a facility-based clinician or group does not meet the case minimum for any cost performance category measure and the cost performance category weight is redistributed to the quality performance category so the quality performance category score alone determines the score out of the available 60 points. Table 53 shows these two scenarios.

TABLE 53: Two Scenarios for a Facility-based Clinician or Group which Could occur under current policy

Quality Performance Category Percent Score	Cost Performance Category Percent Score	Combined Quality and Cost Performance Category Scores (out of 60 available points)
75%	50%	(45 points x 0.75) + (15 points x 0.5) = 41.25
75%	N/A (no cost measures met case minimum)	(60 points x 0.75) = 45

In the CY 2020 PFS final rule, we established a redistribution policy for the CY 2020 MIPS performance period/CY 2022 MIPS payment year at § 414.1380(c)(2)(ii)(D), for scenarios when the cost performance category weight is redistributed to the Promoting Interoperability performance category, as well as to the quality performance category (84 FR 63028). Under this policy, the weights of the combined quality and cost performance categories could be different for a clinician or group under facility-based measurement and outside of facility-based measurement in circumstances in which the clinician or group was not scored on the cost performance category outside of facility-based measurement but was scored on all other performance categories. Table 54 shows the scenario in which the combined weights of the quality and cost performance categories differ if cost is included, which occurs when the cost performance category is redistributed and all other categories are scored.

TABLE 54: Scenario in which the Combined Weights of the Quality and Cost Performance Categories Differ if Cost is Included

Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability	Combined Quality and Cost
Scores for all four performance categories	45	15	15	25	60
No cost	55	0	15	30	55

We established similar redistribution policies for CY 2021 MIPS performance period/CY 2023 MIPS payment year and CY 2022 MIPS performance period/CY 2024 MIPS payment year at § 414.1380(c)(2)(ii)(E) and (F) in that same rule (84 FR 63029 through 63031), which also described situations where the combined weight of the cost and quality performance categories was not always consistent. For more on the background and proposed policies related to redistribution of performance categories, please see section IV.A.3.e.(2)(b)(iii) of this proposed rule.

Based on inquires we received from clinicians who were eligible for facility-based measurement, we believe our policy for determining the combined quality and cost performance category scores via facility-based measurement and outside of facility-based measurement is not ideal because it could result in a facility-based clinician or group receiving a lower final score

than they would otherwise receive outside of facility-based measurement. We considered whether this more complex consideration of the scores and the weights in the performance categories necessitated a reconsideration of an opt-in requirement for facility-based measurement. However, we believe that establishing such a requirement would create administrative burden for clinicians and groups.

Instead of adding an opt-in requirement, we propose a new policy to determine the MIPS final score for clinicians and groups who are eligible for facility-based measurement. We propose at § 414.1380(e)(6)(vi)(B) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission. Under this proposed policy, we would calculate two final scores for clinicians and groups who are facility-based. One score would be based on the clinician or group's performance and the weights of the performance categories if facility-based measurement did not apply, and the other would be based on the application of facility-based measurement. The example below shows how this proposed policy would apply for a facility-based group that did not meet the case minimum for any of the cost measures but was scored on all other performance categories.

TABLE 55: Application of Proposed Policy for a Facility-based Group that Did Not Meet the Case Minimum for any of the Cost Measures but was Scored on All Other Performance Categories

Scenario	Quality Points/available points	Cost points/available points	Improvement Activities points/available points	Promoting Interoperability points/ available points	Final Score
Facility-based	26/30	27/30	15/15	20/25	88/100
Not facility-based	52/55	0/0	15/15	24/30	91/100

As a result of this proposed policy, the group in this example would receive a final score on the basis of their performance outside of facility-based measurement because they have obtained a higher final score through the combination of their submitted quality measures, submitted improvement activities and submitted promoting interoperability measures.

We request comments on this proposal.

f. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score used to determine MIPS payment adjustments, we refer readers to the CY 2021 PFS final rule (85 FR 84917 through 84926), CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343). In this proposed rule, we are proposing: (1) To select the mean as our methodology for calculating the performance threshold; (2) to establish the performance threshold for the 2024 MIPS payment year using 2019 MIPS payment year data; (3) to establish the additional performance threshold for exceptional performance for the 2024 MIPS payment year; and (4) to update the scoring hierarchy to include subgroups. In addition, we are including information about our expected timeframe for providing MIPS performance feedback to clinicians for the performance period in 2020.

(2) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

We have applied these special rules for the past 5 years to provide for a gradual and incremental transition to the year 6 performance threshold. For further information on established

performance threshold policies we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77333 through 77338), CY 2018 Quality Payment Program (82 FR 53787 through 53794), CY 2019 PFS final rule (83 FR 59880 through 59883), the CY 2020 PFS final rule (84 FR 63031 through 63037), and the CY 2021 PFS final rule (85 FR 84919 through 84923). We codified the performance thresholds for each of the first 5 years of MIPS at § 414.1405(b)(4), (5), (6), (7), and (8) as presented in Table 56.

TABLE 56: Performance Thresholds for the 2019 MIPS Payment Year through 2023 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year
	Year 1	Year 2	Year 3	Year 4	Year 5
Performance Threshold	3 points	15 points	30 points	45 points	60 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points

In the CY 2020 PFS final rule (84 FR 63031 through 63037) at § 414.1405(b)(7) and (8), we finalized the performance thresholds for the 2022 and 2023 MIPS payment years at 45 and 60 points, respectively, an increase of 15 points each year until the 2024 MIPS payment year, for which we estimated that the performance threshold would be 74.01 points. We believe that this approach effectively provided for a gradual and incremental transition to the performance threshold we had estimated for the 2024 MIPS payment year, as required by the statute.

Beginning with the 2024 MIPS payment year, section 1848(q)(6)(D)(i) of the Act requires the performance threshold to be the mean or median (as selected by the Secretary) of the final scores for all MIPS eligible clinicians with respect to a prior period specified by the Secretary. That section also provides that the Secretary may reassess the selection of the mean or median every three years. Thus, we considered whether to use the mean or median as the methodology for determining the performance threshold. We would use this methodology to determine a performance threshold for each of the following three years: The 2024 MIPS payment year, 2025 MIPS payment year, and 2026 MIPS payment year. We would then reassess and establish the methodology (mean or median) that we would use for each of the next 3 years (2027 MIPS payment year, 2028 MIPS payment year, and 2029 MIPS payment year). At the time of publication of this proposed rule, we have final score data from the 2017 MIPS performance period/2019 MIPS payment year through the 2019 MIPS performance period/2021 MIPS payment year to use in our assessment of whether to use the mean or median as our methodology for the next 3 years.

From our review of the available data, we have identified the mean and median final scores for each of the 2019 through 2021 MIPS payment years, as shown in Table 57. These six values represent all available prior year mean and median final scores that could be utilized for the 2024 MIPS payment year performance threshold.

TABLE 57: Possible Values for the 2024 MIPS Payment Year Performance Threshold

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year
Mean	74.65 Points	87 Points	85.61 Points
Median	89.71 Points	99.63 Points	92.30 Points

As shown in Table 57, using the median final score gives a possible range of performance thresholds from 89.71 points to 99.63 points. Given our performance threshold of 60 points in year 5, these values would result in an increase of 29.71 points to 39.63 points for year 6. Selecting the median of final scores as our methodology would, at a minimum, nearly double the annual increase in the performance threshold of 15 points that we had from year 2 to year 5 of the program. Section 1848(q)(6)(D)(iv) of the Act required that we increase the performance threshold for each of the third, fourth, and fifth years of MIPS to ensure a gradual and incremental transition to the performance threshold we estimated with respect to the sixth year of MIPS. In prior rules we estimated the year six performance threshold to be 74.01 points and used this estimate to determine how to gradually raise the performance threshold (83 FR 59881, 84 FR 63032, 84 FR 40802). Although section 1848(q)(6)(D)(iv) of the Act does not require this approach for the sixth year and subsequent years of MIPS, we believe that it is appropriate to set the performance threshold at a level that is in line with our previous estimates for year 6. We believe that continuing the gradual and incremental increase into year 6 would provide consistency to our stakeholders. After evaluating the possible values shown in Table 57, we believe that using the mean as our methodology would continue this approach.

Using the mean final score as the methodology would yield a possible range of performance thresholds from 74.65 points to 85.61 points (rounded to 75 points and 86 points respectively). Given our performance threshold of 60 points in year 5, these values would result in an increase of 15 points to 26

points for year 6. Given these values and our annual performance threshold increases of 15 points for years 2 to 5 of the program, 75 is the value that is most consistent with the gradual and incremental approach that we have elected to continue. Therefore, we are proposing at § 414.1405(g) that for each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under § 414.1405(b). This methodology will be used for MIPS payment years 2024 through 2026 of the program after which we will reassess the methodology for MIPS payment years 2027 through 2029.

In addition to selecting the methodology (mean or median), section 1848(q)(6)(D)(i) of the Act also requires us to specify a prior period from which we would use the final scores for all MIPS eligible clinicians to calculate the mean or median. As shown in Table 57, the mean final scores are 74.65, 87, and 85.61 points for MIPS payment years 2019 through 2021 respectively. In previous rules (83 FR 59881, 84 FR 63032), we used the MIPS payment year 2019 mean final score to estimate a performance threshold of 74.01 points for year 6 of the program. Our data have been updated to reflect completed targeted reviews since the time we made this estimate, and the mean final score for the 2019 MIPS payment year is now 74.65 points (see Table 57). This value would be an increase of almost exactly15 points from the MIPS payment year 2023 performance threshold of 60 points, which is identical to the increases of the previous three years and consistent with our intention to continue the gradual and incremental approach that has been utilized in prior years. After reviewing the available final score data, we are proposing at § 414.1405(b)(9) to use the MIPS payment year 2019 as the prior period and the rounded mean final score of 75 points as the year 6 performance threshold. When we establish the performance threshold for future MIPS payment years in future rulemaking, we will reassess using the mean final score for MIPS payment year 2019 as mean final scores for subsequent years become available.

We request comments on these proposals, as well as the alternative methodology of the median that we considered but did not propose. Additionally, we request comments on calculating the performance threshold using an alternative year's final scores that we considered but did not propose.

(3) Additional Performance Threshold for Exceptional Performance

Section 1848(q)(6)(D)(ii) of the Act requires the Secretary to compute, for each year of the MIPS (beginning with the 2019 MIPS payment year and ending with the 2024 MIPS payment year), an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors for exceptional performance under section 1848(q)(6)(C) of the Act. For each such year, the Secretary shall apply either of the following methods for computing the additional performance threshold: (1) The threshold shall be the score that is equal to the 25th percentile of the range of possible final scores above the performance threshold determined under section 1848(q)(6)(D)(i) of the Act; or (2) the threshold shall be the score that is equal to the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to the prior period described in section 1848(q)(6)(D)(i) of the Act. Under section 1848(q)(6)(C) of the Act, a MIPS eligible clinician with a final score at or above the additional performance threshold will receive an additional MIPS payment adjustment factor and may share in the $500 million of funding available for the year under section 1848(q)(6)(F)(iv) of the Act. We note that under section 1848(q)(6)(F)(iv) of the Act, funding is available for additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act only through the 2024 MIPS payment year, which is the sixth year of the MIPS program.

In the CY 2020 PFS final rule (84 FR 63037 through 63040), we used the special rule under section 1848(q)(6)(D)(iii) of the Act to set the additional performance threshold at 85 points for the 2022 and 2023 MIPS payment years. We note that the special rule under section 1848(q)(6)(D)(iii) of the Act applies only to the initial 5 years of MIPS, so we cannot use that rule to establish the additional performance threshold for the 2024 MIPS payment year. As noted above, under section 1848(q)(6)(D)(ii) of the Act, we may set the additional performance threshold at either: (1) The 25th percentile of the range of possible final scores above the performance threshold, or (2) the 25th percentile of the actual final scores for MIPS eligible clinicians with final scores at or above the performance threshold with respect to the prior period described in section 1848(q)(6)(D)(i) of the Act.

TABLE 58: Possible Values for the 2024 Payment Year Additional Performance Threshold

	2019 MIPS Payment Year Mean	2019 MIPS Payment Year Median	2020 MIPS Payment Year Mean	2020 MIPS Payment Year Median	2021 MIPS Payment Year Mean	2021 MIPS Payment Year Median
25th Percentile of Possible Scores	81.26	92.51	90.26	100	89.51	94.01
25th Percentile of Actual Scores	88.94	94.84	98.33	100.00	91.83	94.70

For illustrative purposes, the possible additional performance thresholds are shown in Table 58. Note that mean or median refers to the methodology for calculation of the performance threshold. As can be seen in Table 58, the potential values for the additional performance threshold range from a low of 81.26 to a high of 100. However, to remain consistent with our gradual and incremental approach, we have proposed to use the mean as our methodology for setting the performance threshold during the next 3 years and we have proposed to use the final score data from MIPS payment year 2019. The selection of the mean for the methodology and final score data from the 2019 MIPS payment year leaves us with the options in the first column of Table 58 for where we can set the additional performance threshold.

As stated above, with a proposed performance threshold of 75 points for the 2024 MIPS payment year based on final scores for the 2019 MIPS payment year, the calculation methods in section 1848(q)(6)(D)(ii) of the Act give us two possible options for where we can set the additional performance threshold for MIPS payment year 2024. The first calculation method (described in section 1848(q)(6)(D)(ii)(I) of the Act),

using the range of possible final scores above the proposed performance threshold for the 2024 MIPS payment year, yields a value of 81.26 points (the 25th percentile of the range of 75.01 to 100). The calculation is as follows: 75.01 + [(100–75.01) * 0.25] = 81.26. The second calculation method (described in section 1848(q)(6)(D)(ii)(II) of the Act), the 25th percentile of the actual final scores for the 2019 MIPS payment year at or above the proposed performance threshold for the 2024 MIPS payment year, yields a value of 88.94. For the second calculation method, we would apply the 25th percentile calculation of (n+1)p/100 to the 2019 MIPS payment year final score data that are at or above 75.

We considered using each of these methods, but we do not believe that it would be appropriate to lower the additional performance threshold to 81.26 points from its present value of 85 points. Maintaining or increasing the additional performance threshold likely would serve as a greater incentive to clinicians to continue to improve their performance on the MIPS measures and activities and to achieve exceptional performance. We believe that an additional performance threshold of 88.94 points rounded to 89 points is appropriate. This is an increase of 4 points from the prior year, which we believe would be a gradual increase. Therefore, using the second calculation method described above, we are proposing at § 414.1405(d)(7) to set the additional performance threshold for the 2024 MIPS payment year at 89 points.

We request comments on these proposals as well as the alternative additional performance thresholds listed that we considered but did not propose.

(4) Example of Adjustment Factors

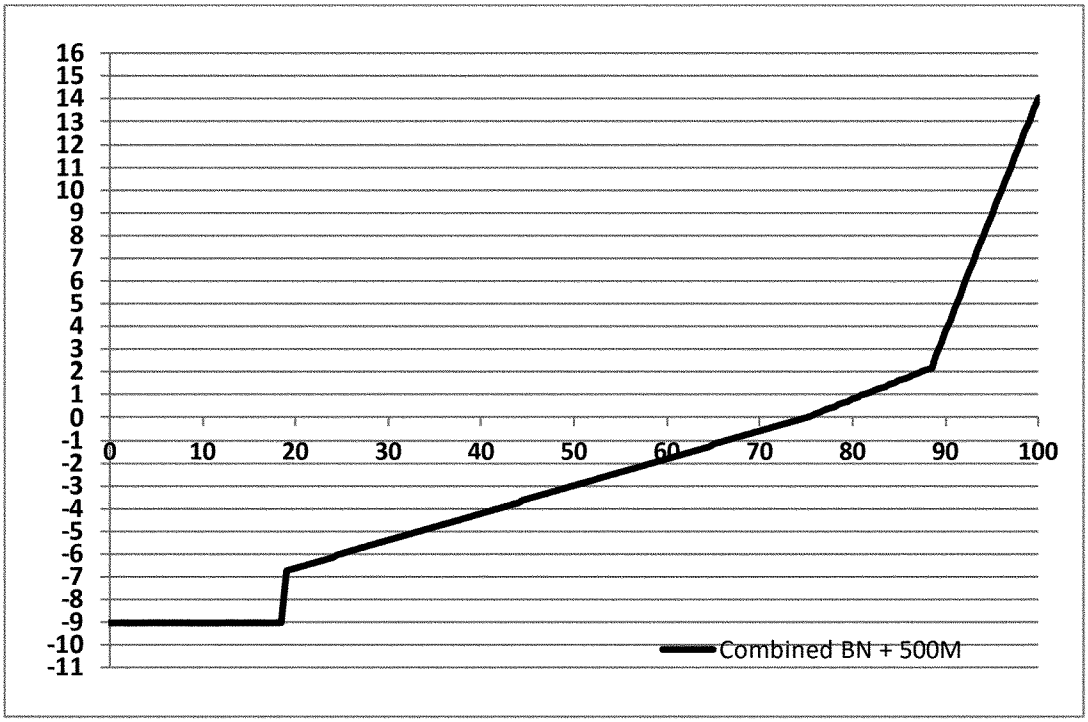
Figure A provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our proposed policies for the 2024 MIPS payment year. In Figure A, the performance threshold is set at 75 points. The applicable percentage is 9 percent for the 2024 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2024 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 18.75 points based on the proposed performance threshold of 75 points for the 2024 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 9 percent for the 2024 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 9 percent. If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be greater than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 75 points (which is the proposed performance threshold) would receive a neutral MIPS payment adjustment. Because the performance threshold is 75 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 9 percent.

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Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2024 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustartive. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is inteded to ensure budget neutrality, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 89 points would also receive an additional adjustment factor for expectional performance. The additional adjustment factor starts at 0.5 percent, cannot exceed 10 percent, and is also mulitiplied by a scaling factor that is greather than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustartive as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 59 illustrates the changes in payment adjustment based on the final policies from the CY 2021 PFS final rule (85 FR 84923 through 84925) for the 2023 MIPS payment year and the proposed policies for the 2024 MIPS payment year, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 59: Illustration of Point System and Associated Adjustments Comparison between the Finalized 2023 MIPS Payment Year and the Proposed 2024 MIPS Payment Year

2023 MIPS Payment Year		2024 MIPS Payment Year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-15.0	Negative 9%	0.0-18.75	Negative 9%
15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	18.76-74.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
60.0	0% adjustment	75.0	0% adjustment
60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	75.01-88.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance	89.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 75.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 89.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance

(5) Final Score Hierarchy Used in Payment Adjustment Calculation

In the CY 2021 PFS final rule (85 FR 84917 through 84919), we modified the final score hierarchy that applies when more than one final score is associated with a TIN/NPI, as displayed in Table 60. Beginning with the 2021 performance period/2023 MIPS payment year, if a TIN/NPI has a virtual group final score associated with it, we use the virtual group final score to determine the MIPS payment adjustment. If a TIN/NPI does not have a virtual group final score associated with it, we use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment.

TABLE 60: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, an APP final score, a group final score, and/or an individual final score.	Virtual group final score.
TIN/NPI has an APM Entity final score, an APP final score, a group final score, and/or an individual final score, but is not in a virtual group.	The highest of the available final scores.

In section IV.A.3.b.(3) of this proposed rule, we are proposing policies applicable to subgroups, including a definition of a subgroup at § 414.1305 as a subset of a group which contains at least one MIPS eligible

clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI. Each clinician in a subgroup would be identifiable by a unique TIN/NPI combination just as in any MIPS group or APM Entity. In addition, a clinician, group, subgroup, or APM Entity could choose more than one MIPS reporting option for a performance period. A clinician, group, subgroup, or APM Entity could choose to report through MVPs, traditional MIPS, and/or the APP (assuming they are eligible for each of these reporting options) for a performance period. As a result, there could be more than one final score for a clinician, group, subgroup, or APM Entity for a performance period from MVPs, traditional MIPS, and/or the APP. Therefore, we propose to update the scoring hierarchy to include subgroups and to specify that the scoring hierarchy would apply with respect to any available final score that is associated with a TIN/NPI from MVPs, traditional MIPS, and/or the APP. The proposed updated scoring hierarchy can be seen in Table 61. We are seeking comment on this proposal.

TABLE 61: Proposed Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, a group final score, a subgroup final score, and/or an individual final score, from MVPs, traditional MIPS, and/or the APP.	Virtual group final score.
TIN/NPI has an APM Entity final score, a group final score, a subgroup final score, and/or an individual final score, from MVPs, traditional MIPS, and/or the APP. The TIN/NPI is not in a virtual group.	The highest of the available final scores.

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g. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

On July 1, 2018, we provided the first performance feedback for the Quality Payment Program. The second performance feedback was provided on July 1, 2019. In the CY 2021 PFS proposed rule (85 FR 50321), we noted that we aim to provide performance feedback on or around July 1 of each year, but due to the Public Health Emergency (PHE) and COVID–19, we estimated that we would provide performance feedback for the performance period in 2019 in late July or early August of 2020. The third performance feedback (for the 2019 performance period) was provided on August 5, 2020. We note that similar to the 2019 performance period, due to the PHE for COVID–19, we may provide performance feedback for the 2020 performance period after July 1, 2021. Although we aim to provide performance feedback on or around July 1 of each year, it is possible that the release date could be later than July 1 depending on the circumstances. We estimate that we will provide performance feedback for the performance period in 2020 in early August of 2021, although this timeframe could be subject to change. We direct readers to *qpp.cms.gov* for more information.

h. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (85 FR 84926 through 84947) for our previously established policies regarding third party intermediaries.

In the CY 2022 PFS proposed rule, we propose to make several changes: (1) Reorganization and consolidation of § 414.1400 generally; (2) new third party intermediaries general requirements; (3) new requirements specific to both QCDR and qualified registries; (4) new requirements specific to only QCDRs; and (5) remedial action and termination of third parties.

(1) Proposed Reorganization and Consolidation of § 414.1400 Generally

We recognize that many of our policies for third party intermediaries are similar or verbatim, and yet in prior rules, we have described them separately. To minimize the lengthiness and burden of reading our policies, we are proposing to consolidate our regulatory text under § 414.1400. To be clear, our proposed updates would not change previously finalized requirements for third party intermediaries, but would bring more clarity and simplicity to the regulatory text. These proposed changes are discussed by topic in more detail below. We also note that in several places at § 414.1400 the regulation text was only updated to reflect both the applicable MIPS performance period/MIPS payment year.

(a) Proposed Reorganization for Requirements Related to MIPS Performance Categories That Must be Supported by Third Party Intermediaries

We previously established in the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), and further revised in the Quality Payment Program provisions in the CY 2019 and

CY 2020 PFS final rules ((83 FR 60088 and 84 FR 63049 through 63052, respectively), and further clarified our requirements of QCDRs, qualified registries, and health IT vendors with regards to submitting data for purposes of the MIPS program in the Quality Payment Program provisions in the CY 2021 PFS final rule, at § 414.1400(a)(2), for our current policy regarding the types of MIPS data that third party intermediaries may submit. Our current requirements at § 414.1400(a)(2) state, beginning with the CY 2021 MIPS performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories, and Health IT vendors must be able to submit data for at least one of the following MIPS performance categories: Except as provided under (a)(2)(ii), QCDRs, qualified registries, and health IT vendors must be able to submit data for all of the following MIPS performance categories:

- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries and Health IT vendors, QCDR measures;

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*)).

++ Health IT vendors that do not support MIPS Value Pathways must be able to submit data for at least one of the MIPS performance categories described in paragraphs (a)(2)(i)(A) through (C) of this section.

++ Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or § 414.1380(c)(2)(i)(C)(*1*) through (*7*) or § 414.1380(c)(2)(i)(C)(*9*)).

In an effort to simplify, we propose reorganizing existing language at § 414.1400(a)(2). Specifically, we propose providing updates to separately identify and provide clarity to data submission requirements since data requirements vary based on third party intermediary type and to provide clarification to exceptions to Promoting Interoperability for virtual groups and subgroups. We propose the following updates:

- To revise and redesignate existing paragraph at § 414.1400(a)(2) through (a)(2)(i) to proposed paragraphs § 414.1400(b)(1)(i) and (c)(1) through (c)(1)(i) to state the following:
- To state at proposed § 414.1400(b)(1)(i), beginning with the CY 2021 MIPS performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories:
- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries, QCDR measures.

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

++The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*)).

- To state at proposed § 414.1400(c)(1), beginning with the CY 2021 MIPS performance period/2023 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:
- To state at proposed § 414.1400(c)(1)(i) through (c)(1)(i)(B), health IT vendors that support MVPs must be able to submit data for all of the MIPS performance categories:
- Quality, except:

++ The CAHPS for MIPS survey; and

++ QCDR measures;

- Improvement activities; and
- To revise and redesignate existing paragraph at § 414.1400(a)(2)(iii) to proposed paragraph § 414.1400(c)(1)(i)(C) state, Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

++ The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

- To revise and redesignate existing paragraph at § 414.1400(a)(2)(ii) to proposed paragraph § 414.1400(c)(1)(ii) to state, health IT vendors that do not support MVPs must be able to submit data for at least one of the MIPS performance categories described in paragraphs (c)(1)(i) through (iii) of this section.
- We propose to create a new requirement at § 414.1400(c)(1)(iii) for health IT vendors to support MVPs. For more information on this proposal, please refer to section ''proposed new requirement for third party intermediaries to support MVPs and the APP'' below at IV.A.3.h.(2)(b)(i).
- To move the current Health IT vendor requirements from paragraphs § 414.1400 (a)(2)(ii) through (iii) and § 414.1400 (d) to a proposed new section applicable to Health IT vendor requirements at § 414.1400(c). This will separately identify and provide clarity to data submission requirements specific to Health IT vendors.
- To move the current CMS-approved survey vendor requirements from paragraphs (a)(3) and (e) to a proposed new section applicable to CMS-approved survey vendor requirements at § 414.1400(d). We propose to the redesignate paragraph (a)(3) current requirements to paragraph (d)(1) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category. For the current requirements at paragraph (e), we propose to move up those requirements to paragraph (d)(2).
- To redesignate paragraph (a)(4) as paragraph (a)(2).
- To redesignate paragraph (a)(5) as paragraph (a)(3).

We request public comment on our proposals.

(b) Proposed Reorganization for Requirements Related QCDR and Qualified Registries Self-Nomination

We are proposing to consolidate and redesignate the existing language at § 414.1400(b)(1) and (c)(1) to proposed § 414.1400(b)(2) to reference both QCDR and qualified registries. We are proposing this consolidation to provide clarity and alignment with the aforementioned proposals and consolidate the duplicative criteria of QCDRs and qualified registries. As discussed below, we are also proposing to consolidate and redesignate the performance feedback requirements previously at existing § 414.1400(b)(1) and (c)(1) to § 414.1400(b)(3)(iii). We propose to state at § 414.1400 (b)(2), Self-nomination. For the 2018 and 2019 performance periods/2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR or qualified registry must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2020 MIPS performance period/2022 MIPS payment year and future years, entities seeking to qualify as a QCDR or qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR or

qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2019 MIPS performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

We also propose removing the last two sentences of existing § 414.1400(b)(1), which are duplicative with existing § 414.1400(b)(3)(iii). We propose consolidating this language with existing paragraph (b)(3)(iii). We request public comment on our proposals.

(c) Proposed Reorganization for Requirements Related to QCDR and Qualified Registries Conditions for Approval

We refer readers to existing § 414.1400(b)(2) for QCDR conditions for approval and existing § 414.1400(c)(2) for qualified registries conditions for approval. In this proposed rule, we are proposing the following in order to better organize, consolidate the duplicative criteria of QCDRs and qualified registries, and refer to both ''QCDR and qualified registry'' instead of one or the other:

- We propose to redesignate existing paragraph (b)(2) to proposed paragraph (b)(3) and revising the paragraph heading as, *Conditions for approval.*
- We also propose updating the reference to both QCDR and qualified registry in proposed paragraph (b)(3).
- We propose to revise to include both QCDR and qualified registry and redesignate existing paragraph (b)(2)(i) to proposed paragraph (b)(3)(i).
- We propose to revise and redesignate existing paragraph (b)(2)(ii) to proposed paragraph (b)(3)(ii). We also propose to extend our policy for collaboration. For more information on this proposal, please refer to section ''collaboration of entities to become a QCDR and proposal to extend policy for collaboration of entities to become a qualified registry'' below at section IV.A.3.h.(3)(a)(ii) of this proposed rule.
- As discussed above, we are proposing to consolidate and redesignate the performance feedback requirements previously at existing § 414.1400(b)(1) and (c)(1) to § 414.1400(b)(3)(iii). Furthermore, to consolidate similar performance feedback requirements, we also propose to revise and redesignate existing paragraph (b)(2)(iii) to proposed paragraph (b)(3)(iii) to state, beginning with the 2021 MIPS performance period/2023 MIPS payment year, require the QCDR or qualified registry must to provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the reporting period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).
- We propose to consolidate and redesignate paragraphs (b)(2)(iv) and (c)(2)(iii) in their entirety, into a new paragraph (b)(3)(v), and to correct a typographical error in which the word ''MIPS'' was omitted in the first sentence.
- We propose to consolidate and redesignate paragraphs (b)(2)(v) and (c)(3)(iv), in their entirety, into a new paragraph (b)(3)(vi).

We invite public comment on our proposals.

(d) Proposed Reorganization for Requirements Related to QCDR Measures

(i) Proposed Reorganization for Requirements Related to QCDR Measures for the Quality Performance Category

We refer readers to existing language at § 414.1400(b)(3) for QCDR measures for the quality performance category. We currently define ''QCDR measure'' at existing § 414.1400(b)(3). We recognize that the QCDR measure definition is referred to throughout our policies and that it is not specific to § 414.1400(b)(3) or third party intermediaries. Therefore, to provide further clarity and to better align with the current policy, we propose moving the QCDR measure definition to the definitions section at § 414.1305. We are also proposing the following revisions to better organize regulation text at § 414.1400(b)(4) and to update cross-references to correspond to the new section numbers as reflected in this proposed rule:

- We propose to redesignate paragraphs (b)(3)(i), (b)(3)(i)(A), and (b)(3)(i)(B) to definitions at § 414.1305.
- We propose to revise and redesignate existing paragraphs at (b)(3)(ii) to proposed paragraphs (b)(4)(i) to state, for the 2018 MIPS performance period/2020 MIPS payment year and future years, at the time of self-nomination an entity seeking to become a QCDR must submit the following information for any measure it intends to submit for the payment year:

++ For MIPS quality measures, the entity must submit specifications including the MIPS measure IDs and specialty-specific measure sets, as applicable.

+ For QCDR measures, the entity must submit for CMS-approval measure specifications including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for that QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

- We also propose adding a header to state, ''QCDR measure self-nomination requirements''. We believe adding a heading will help readers clearly distinguish QCDR measure self-nomination requirements.
- We propose moving existing paragraph at (b)(3)(iii) in its entirety to proposed paragraph (b)(4)(ii) and adding a header to state, ''QCDR measure submission requirements''. We believe adding a heading will help readers clearly distinguish QCDR measure submission requirements.
- We propose moving existing paragraphs at (b)(3)(v) through (v)(C)(*1*) in its entirety, to proposed paragraph (b)(4)(iii) through (b)(4)(iii)(A)(*3*).
- We propose to revise and redesignate existing paragraph at (b)(3)(v)(C)(*2*) to proposed paragraph (b)(4)(iii)(A)(*3*)(*i*) to state, to be included in an MVP for the 2022 MIPS performance period/2024 MIPS payment year and future years, a QCDR measure must be fully tested.
- We propose moving existing paragraph at (b)(3)(vii) in its entirety, to proposed paragraph (b)(4)(iv).

(ii) Proposed Reorganization for Requirements Related to QCDR Measure Approval Criteria

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375) and the Quality Payment Program provisions in the CY 2020 PFS final rule (84 FR

63059), where we finalized existing § 414.1400(b)(3)(v).

We propose to reorganize and make minor updates to the existing requirements at § 414.1400(b)(3)(v) to proposed § 414.1400(b)(4)(iii). We propose to reorganize the existing requirements so that QCDR measure approval at § 414.1400(b)(3)(v) is discussed before QCDR measure considerations at § 414.1400(b)(3)(iv). Therefore, we propose the following revisions:

• To revise and redesignate existing paragraph (b)(3)(v) ''QCDR measure requirement for approval include'' to proposed paragraph (b)(4)(iii) and add a heading to state, ''QCDR measure approval criteria''. We believe adding a heading will help readers clearly distinguish QCDR measure approval criteria. We also propose to include the following updates:

++ Move existing (b)(3)(v) to proposed revised paragraph (b)(4)(iii)(A) to state, QCDR measure requirements for approval are.

++ Move existing paragraph (b)(3)(v)(A) in its entirety to proposed paragraph (b)(4)(iii)(A)(*1*).

++ Move existing paragraph (b)(3)(v)(B) in its entirety to proposed paragraph (b)(4)(iii)(A)(*2*).

++ Revise existing paragraphs (b)(3)(v)(C) and (b)(3)(v)(C)(*1*) to proposed paragraph (b)(4)(iii)(A)(*3*) to state, beginning with the 2022 MIPS performance period/2024 MIPS payment year, all QCDR measures must meet face validity. To be approved for the 2023 MIPS performance period/2025 MIPS payment year, all QCDR measures must be must meet face validity for the initial MIPS payment year for which it is approved. For subsequent years, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

++ Move existing paragraph (b)(3)(v)(C)(*2*) in its entirety to proposed paragraph (b)(4)(iii)(A)(*3*)(*i*).

++ Move existing paragraph (b)(3)(v)(D) in its entirety to proposed paragraph (b)(4)(iii)(A)(*4*).

++ Move existing paragraph (b)(3)(v)(E) in its entirety to proposed paragraph (b)(4)(iii)(A)(*5*).

We invite public comment on our proposals.

(iii) Proposed Reorganization for Requirements Related to QCDR Measure Considerations for Approval

We refer readers to the Quality Payment Program provisions in the CY 2019 PFS final rule (84 FR 63198 through 63199), where we finalized existing § 414.1400(b)(3)(iv) ''QCDR measure considerations for approval''. We propose to reorganize and make minor updates to the language at existing § 414.1400(b)(3)(iv) to proposed § 414.1400(b)(4)(iii)(B). We propose to reorganize the existing requirements so that QCDR measure approval at § 414.1400(b)(3)(v) is discussed before QCDR measure considerations at § 414.1400(b)(3)(iv).

We also propose to redesignate existing § 414.1400(b)(3)(vi) to proposed § 414.1400(b)(4)(iii)(C). Specifically, we propose the following revisions:

• To revise and redesignate existing paragraph (b)(3)(iv) ''QCDR measure considerations for approval include'' to proposed paragraph (b)(4)(iii)(B) ''QCDR measure considerations for approval include, but are not limited to''.

• Move existing paragraph (b)(3)(iv)(A) in its entirety to proposed paragraph (b)(4)(iii)(B)(*1*).

• Move existing paragraph (b)(3)(iv)(B) in its entirety to proposed paragraph (b)(4)(iii)(B)(*2*).

• Move existing paragraph (b)(3)(iv)(C) in its entirety to proposed paragraph (b)(4)(iii)(B)(*3*).

• Move existing paragraph (b)(3)(iv)(D) in its entirety to proposed paragraph (b)(4)(iii)(B)(*4*).

• Move existing paragraph (b)(3)(iv)(E) in its entirety to proposed paragraph (b)(4)(iii)(B)(*5*).

• Move existing paragraph (b)(3)(iv)(F) in its entirety to proposed paragraph (b)(4)(iii)(B)(*6*).

• Move existing paragraph (b)(3)(iv)(G) in its entirety to proposed paragraph (b)(4)(iii)(B)(*7*).

• Revise and consolidate existing paragraph (b)(3)(iv)(G)(*1*) to proposed paragraph (b)(4)(iii)(B)(*7*)(*i*) to state that QCDR link their QCDR measures as feasible to at least one cost measure, improvement activity, or an MVP at the time of self-nomination.

• Move existing paragraph (b)(3)(iv)(G)(*2*) in its entirety to proposed paragraph (b)(4)(iii)(B)(*7*)(*ii*).

• Move existing paragraph (b)(3)(iv)(H) in its entirety to proposed paragraph (b)(4)(iii)(B)(*8*).

• Move existing paragraph (b)(3)(iv)(I) in its entirety to proposed paragraph (b)(4)(iii)(B)(*9*).

• Move existing paragraph (b)(3)(iv)(J) in its entirety to proposed paragraph (b)(4)(iii)(B)(*10*).

• Move existing paragraph (b)(3)(iv)(J)(2) to proposed paragraph Reserve (b)(4)(iii)(B)(*10*)(*ii*).

• Move existing paragraph (b)(3)(vi) in its entirety to proposed paragraph (b)(4)(iii)(C).

We invite public comment on our proposals.

(iv) QCDR Measure Rejection Criteria

We refer readers to the existing requirements at § 414.1400(b)(3)(vii). We propose reorganizing existing requirements at § 414.1400(b)(3)(vii) to proposed § 414.1400(b)(4)(iv). Therefore, we propose the following revisions:

• To revise and redesignate existing paragraph (b)(3)(vii) ''QCDR measure rejection criteria'' to proposed paragraph (b)(4)(iv) and add a heading to state, *QCDR measure rejection criteria.* We believe adding a heading will help readers clearly distinguish measure rejection criteria.

We also propose to include the following updates:

• To move existing paragraph (b)(3)(vii) to proposed paragraph (b)(4)(iv) to state, *QCDR measure rejection criteria.* Beginning with the 2020 MIPS performance period/2022 MIPS payment year, QCDR measure rejection considerations include, but are not limited to.

• Move existing paragraphs (b)(3)(vii)(A) through (L) in their entirety to proposed (b)(4)(iv)(A) through (L).

We invite public comment on our proposals.

(e) Proposed Reorganization for Requirements Related to Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548), CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), and the CY 2021 PFS final rule (85 FR 84930 through 84937) for previously finalized policies for remedial action and termination of third party intermediaries. With the proposed updates being made at § 414.1400, we propose to redesignate the following sections:

• We propose to redesignate current paragraph (f) as paragraph (e) and to update cross-references to correspond to the new section numbers as reflected in this proposed rule.

• We also propose to redesignate current paragraph (g) as paragraph (f) and to update cross-references to correspond to the new section numbers as reflected in this proposed rule.

We invite public comment on our proposals.

(2) Third Party Intermediaries General Requirements

We refer readers to previously established § 414.1400(a) and the CY 2017 Quality Payment Program final

rule (81 FR 77363 through 77364), and as further revised in the CY 2019 PFS final rule (83 FR 60088), CY 2020 PFS final rule (84 FR 63049 through 63052), CY 2021 PFS final rule (85 FR 84926 through 84947) for our established policy regarding third party intermediaries general requirements.

In this proposed rule, we propose a couple changes for third party intermediaries: (1) Third party intermediary submissions for APM Entities; and (2) MIPS performance categories that must be supported by third party intermediaries. We are also requesting comment on third party intermediaries that derive data from CEHRT. These proposals and request for comment are discussed in more detail below.

(a) Third Party Intermediary Submissions for APM Entities

As finalized in the Quality Payment Program provisions in the CY 2021 PFS final rule (85 FR 84895), APM Entities now have the option of reporting to MIPS on behalf of the MIPS eligible clinicians participating in their APM Entity. They have the option of reporting to traditional MIPS or via the APP (85 FR 84859). APM Entities have historically used Third Party Intermediaries for submitting their quality measures to their APMs, rather than to MIPS, however, these third party intermediaries now have the opportunity to submit these data for purposes of MIPS.

In this proposed rule, we are proposing to add APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all participants in MIPS.

We note that the Promoting Interoperability performance category is scored for APM Entities based on data submitted by the participant MIPS eligible clinicians and groups as described at § 414.1317(b)(1), and therefore would not be required to be submitted by the third party intermediary on behalf of the APM Entity.

We request comment on this proposal.

(b) MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to previously established § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), and as further revised in the CY 2019 PFS final rule (83 FR 60088), CY 2020 PFS final rule (84 FR 63049 through 63052), CY 2021 PFS final rule (85 FR 84926 through 84947) for our established policy regarding the types of MIPS data that third party intermediaries may submit.

In this proposed rule, we are proposing new requirements in alignment with our proposals in section IV.A.3.b. of this proposed rule to adopt MVPs and subgroups.

(i) Proposed New Requirement for Third Party Intermediaries To Support MVPs and the APP

As described in the Quality Payment Program provisions finalized in the CY 2021 PFS final rule (85 FR 84849), MVPs should include measures and activities from the quality, cost, improvement activities, and Promoting Interoperability performance categories. As described in section IV.A.3.b. of this proposed rule, we discuss our proposals related to furthering our transition to MIPS Value Pathways (MVPs). As MVPs are implemented, proposed beginning with the 2023 MIPS performance period/2025 MIPS payment year, we believe it is important to also propose the methods in which an MVP participant may report on an MVP or the APP. Since QCDRs, qualified registries, and health IT vendors are required under existing § 414.1400(a)(1) to submit data for quality, improvement activities, and promoting interoperability, we believe they would have the experience needed to support MVP and APP reporting.

Therefore, we propose to create a new requirement at § 414.1400(b)(1)(ii) to state that, beginning with the 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. Additionally, we propose to create a new requirement at paragraph § 414.1400(c)(1)(iii) to state that beginning with the 2023 MIPS performance period/2025 MIPS payment year, Health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. Health IT vendors may also support the APP.

Based off historical participation, we are aware that some third party intermediaries (QCDRs and qualified registries) support a single specialty or subspecialty, while others support multiple specialties. Therefore, we believe that it is not appropriate to expect that all third party intermediaries are able to support all MVPs that are implemented in the program. Rather, the third party intermediaries should identify and support MVPs that are relevant to the clinicians and groups they support. We do not believe that CMS-approved survey vendors will be able to support MVP reporting, because they are historically limited, in that they only support the CAHPS for MIPS Survey Measure.

As proposed in section IV.A.3.b of this proposed rule, MVPs would start with the 2023 MIPS performance period/2025 MIPS payment year. We believe this delay in implementation would allow third party intermediaries sufficient time for programming and system preparation for MVP reporting success. We request comment on our proposals.

(ii) Proposed Requirements for All Third Party Intermediaries To Support Subgroup Reporting

As proposed in section IV.A.3.b.(3) of this proposed rule, subgroup reporting would allow clinicians in multispecialty practices to participate in MIPS more meaningfully. Since subgroups would be implemented concurrently with MVPs, it is important that third party intermediaries have the capability to support subgroup reporting of MVPs. As described above, we believe QCDRs, qualified registries, and health IT vendors would have the capacity to support MVP and APP reporting.

In this proposed rule, we propose to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the 2023 MIPS performance period/2025 MIPS payment year. Therefore, we propose to revise § 414.1400(a)(1) to state that MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup or APM Entity by any of the following third party intermediaries: QCDR; qualified registry; health IT vendor; or CMS-approved survey vendor. We believe it is imperative for all third party intermediaries to be able to support subgroup reporting as we envision that to be the future of the program.

While the CAHPS for MIPS survey vendors cannot support MVPs or the APP, we believe they can support the reporting of the CAHPS for MIPS measure within an MVP and the APP, if a subgroup decides to report on that measure. Due to the limited experience, CAHPS for MIPS survey vendors have in quality reporting, we do not believe it is feasible for them to support MVP reporting since MVP reporting would require experience with reporting across the performance categories and the use of several collection types for quality

reporting. However, there may be instances where the CAHPS for MIPS survey measure may be included in an MVP. For example, in the Optimizing Chronic Conditions Management MVP, as described in Appendix 3: MVP Inventory, of this proposed rule. In such instances, if groups or subgroups would like to report this measure, they should be able to utilize a CAHPS for MIPS survey vendor to do so. We believe it is important that all third party intermediaries support subgroup reporting in order to support meaningful quality reporting. We understand that there may be a level of burden to third party intermediaries that are required in supporting subgroup reporting by requiring them to support another clinician type. However, we believe that requiring third party intermediaries to support subgroup reporting will allow for clinicians to participate in a manner that is more meaningful. We note that as proposed in section IV.A.3.b.(4)(f) of this proposed rule, subgroups would have to register through the MVP participant registration process. Third party intermediaries would need to be able to track the subgroup identifiers and support the data submission process accordingly.

We request comments on our proposal.

(c) Request for Comment on Third Party Intermediaries That Derive Data From CEHRT

For third party intermediaries that will be submitting quality measure data on behalf of MIPS eligible clinicians, we believe that EHR systems will be able to provide measure results for a set of providers that are part of a subgroup where required for subgroup reporting. We note that the existing CEHRT definition for eligible clinicians at § 414.1305 includes the 45 CFR 170.315(c)(4) ''Clinical quality measures—filter'' as an optional element. This criterion requires health IT to be able to filter CQM results at both patient and aggregate levels. Moreover, a Health IT Module must be able to filter by a single proposed data element (for example, provider type) or a combination of any of the data elements). Historically, the ''Clinical quality measures—filter'' at 45 CFR 170.315(c)(4)'' (CQM-filter) criterion has been applicable for certified health IT modules supporting quality measurement for participants in certain APMs.

We believe technology certified to this optional criterion could support subgroup reporting via third party intermediaries that derive data from CEHRT by ensuring that an EHR can produce CQM results filtered for a specific group of provider NPIs that are part of a subgroup. These filtered CQM results could then be shared with a third party intermediary, which provides this data for reporting to CMS. However, we also believe health IT developers are offering non-certified functionality that can effectively support reporting of measure results for a subgroup. As a result, we are not proposing any changes at this time to the language in the CEHRT definition for eligible clinicians regarding the ''optional'' status of technology certified to the CQM-filter criterion.

We are interested in general feedback from stakeholders on the current capabilities of third party intermediaries that derive data from CEHRT to successfully receive and transmit data to CMS for CQMs based on subgroups; capabilities of EHR systems to support subgroup reporting, including reporting facilitated by third party intermediaries, and whether requiring the adoption of technology certified to the CQM-filter criterion would help to support subgroup reporting; and challenges which entities may face in meeting requirements to report on subgroups when deriving data from CEHRT. We request feedback on this topic.

(3) New Requirements for Both Qualified Clinical Data Registries (QCDRs) and Qualified Registries

(a) Background

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (85 FR 84926 through 84947) for our previously established policies regarding QCDRs and qualified registries.

In this proposed rule, we propose several changes for both QCDRs and qualified registries: (1) New requirement for approved QCDRs and qualified registries that have not submitted performance data; (2) collaboration of entities to become a QCDR and qualified registry; and (3) data validation audit and targeted audit requirements. These proposals are discussed in more detail below.

(i) Proposed New Requirement for Approved QCDRs and Qualified Registries That Have Not Submitted Performance Data

We require that both QCDRs and qualified registries must have a minimum of 25 participants signed up by the prior performance period at existing § 414.1400(b)(2) and (c)(2). We refer readers to CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (85 FR 84926 through 84947). We identified a number of QCDRs and qualified registries that have continued to self-nominate to become a third party intermediary for the MIPS program, but have not submitted clinician, group or virtual group data to CMS. As the MIPS program continues to mature, we wish to reduce the number of vendors that self-nominate to become a qualified vendor, but do not actively participate in the MIPS program. We believe that maintaining these vendors who do not actively participate does not provide a benefit to the MIPS program, rather it creates stakeholder confusion by including these vendors in our qualified postings.

We are proposing a two-tiered approach to solve this issue. First, we propose to create a new requirement at § 414.1400(b)(3)(vii) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (2017 MIPS performance period/2019 MIPS payment year) through the 2020 MIPS performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. Exceptions to this requirement may occur if data is received for the 2021 MIPS performance period/2023 MIPS payment year. Under this scenario, QCDRs and qualified registries would not need to submit a participation plan for CY 2023 of the self-nomination period. If they do not submit data, their participation plan must be submitted as part of self-nomination for CY 2023 and must be accepted by CMS to continue to be an approved QCDR or qualified registry.

Secondly, we propose to codify a new requirement at paragraph (b)(3)(viii) to state, beginning with the 2024 MIPS performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the

2 years preceding the applicable self-nomination period must submit a participation plan for CMS's approval. For example, for the 2024 MIPS performance period/2026 MIPS payment year, vendors will be required to have submitted performance data for the 2021 and 2022 MIPS performance periods/2023 and 2024 MIPS payment years. Under this proposal, the participation plan must explain the QCDR's or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third party intermediary on behalf of clinicians or groups. The vendor must also explain why they should still be allowed to participate as a qualified vendor. We note that this proposed participation plan was modeled off of the current requirement for QCDR measure participation at existing § 414.1400(b)(3)(iv)(J)(*1*) (redesignated to proposed § 414.1400(b)(4)(iii)(B)(*10*)(*i*)). We request comments on this proposal.

(ii) Collaboration of Entities To Become a QCDR and Proposal To Extend Policy for Collaboration of Entities To Become a Qualified Registry

(A) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77377), we finalized to allow collaboration of entities to become a QCDR based on our experience with the qualifying entities wishing to become QCDRs for performance periods. We stated that we believed our previously finalized policy supporting entity collaboration should be continued under MIPS. Therefore, we discussed that an entity that may not meet the criteria of a QCDR solely on its own, but could do so in conjunction with another entity and would be eligible for qualification through collaboration with another entity. Additionally, we finalized at § 414.1400(b)(2)(ii), specifically for QCDRs, that if the entity uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

For example, an entity, such as a specialty society, that needs technical support may partner with an outside entity such as a health IT vendor to qualify as a QCDR. While entities, such as QCDRs, Health IT vendors, and qualified registries, can collaborate with external organizations, those entities could only do so to meet requirements to be a QCDR. We did not explicitly create a policy for entities to collaborate to meet the requirements to be a qualified registry.

(B) Proposal To Extend to Qualified Registries

We believe we should extend the previously finalized policy to apply to entities who wish to collaborate to become a qualified registry, as well because extending this policy to qualified registries would also help smaller societies that may not have the resources on their own to become a qualified registry. This will allow those societies to be able to partner with other entities to meet the definition of a qualified registry. Therefore, in this proposed rule, we propose to revise and redesignate existing paragraph (b)(2)(ii) to new paragraph (b)(3)(ii) to state, if the entity seeking to qualify as a QCDR or qualified registry uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period. For example, an entity, such as a specialty society, that needs technical support may partner with an outside entity such as a health IT vendor to qualify as a qualified registry. We request comments on this proposal.

(iii) Data Validation Audit and Targeted Audit Requirements

(A) Information Required at the Time of Self-Nomination

In the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367; 81 FR 77383 through 77384) we discussed our expectation for QCDRs and qualified registries to conduct validation on the data they intend to submit for the MIPS performance period. We also discussed that the full self-nomination process would require the following: A submission of basic information, a description of the process the QCDR and qualified registry will use for completion of a targeted audit of a subset of data prior to submission, the provision of a data validation plan along with the results of the executed data validation plan by May 31 of the year following the performance period. Additionally, in the Quality Payment Program provisions in the CY 2021 PFS final rule (85 FR 84930 through 84937; 85 FR 84944 through 84947) at existing § 414.1400(b)(2)(iv) and (v) and § 414.1400(c)(2)(iii) and (iv), we finalized the data validation audit requirements as condition for approval. While we did finalize the requirements for the data validation audits as condition for approval, we did not codify the requirements for QCDR and qualified registries to submit data validation plan during self-nomination along with the results of the executed data validation plan by May 31 of the year following the performance period.

In order to provide clarification and to better align with the previously finalized policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), we propose to codify the following revisions. As stated in previous polices (81 FR 77366 through 77367;81 FR 77383 through 77384), QCDRs and qualified registries are required to submit the results of their data validation plan to CMS by May 31 of the year following the performance period. Therefore, we propose to codify at § 414.1400(b)(3)(v)(G)(*1*) to state that QCDRs and qualified registries must conduct validation on the data they intend to submit for the applicable MIPS performance period, and provide the results of the executed data validation plan by May 31st of the year following the performance period.

Furthermore, QCDRs and qualified registries are required to submit their data validation plan explaining their process of data validation submission annually during self-nomination, and it must be approved by CMS for before use. To provide further clarity and to better align with the existing policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), we also propose to codify a new requirement at § 414.1400(b)(3)(iv) to state that, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency.

As discussed above we propose to codify at § 414.1400(b)(3)(iv) to provide further clarity to better align with previous policies. Therefore, we propose to reorganize at § 414.1400(b)(2)(iv) though (viii) to better align with the above changes. We propose with the following revisions:

- We propose to revise and redesignate existing paragraph (b)(2)(iv) to proposed paragraph (b)(3)(v) to state, that beginning with the 2021 MIPS

performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct annual data validation audits in accordance with this paragraph (b)(3)(v).

- We propose to revise and redesignate existing paragraph (b)(2)(iv)(A) to proposed paragraph (b)(3)(vi)(A) to state that, if a data validation audit under paragraph (b)(3)(v) identifies one or more deficiency or data error, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.
- We propose to revise and redesignate existing paragraph (b)(2)(v) to proposed paragraph (b)(3)(vi) to state that beginning with the 2021 MIPS performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with this paragraph (b)(3)(vi).
- We propose to revise and redesignate paragraph (b)(2)(vi) to proposed paragraph (b)(3)(vii), to state for the 2023 MIPS performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years must submit a participation plan for CMS's approval. This participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.
- We propose to revise and redesignate existing paragraph (b)(2)(vii) to proposed paragraph (b)(4)(viii) to state that beginning with the 2024 MIPS performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS's approval.

(4) New Requirements Specific to QCDRs

(a) Background

We refer readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), the May 8th COVID–19 IFC (85 FR 27594 through 27595), and the CY 2021 PFS final rule (84937 through 84944) for where we previously finalized standards and criteria for QCDRs, specifically QCDR measure requirements. In this section, we propose to update policies related to QCDR measure rejections.

(b) QCDR Measures

(i) QCDR Measure Rejections

(A) Proposed New QCDR Measure Rejection Criteria

We refer readers to the Quality Payment Program provisions in the CY 2020 PFS final rule (84 FR 63070 through 63073) at § 414.1400(b)(3)(vii) where we have previously adopted QCDR measure rejection criteria. In this proposed rule, we are proposing to add two new criteria: (1) QCDR does not have permission to use a QCDR measure; and (2) QCDR not approved or not in good standing. These are discussed in more detail below.

(aa) QCDR Does Not Have Permission To Use a QCDR Measure

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we discussed that beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. We noted that the QCDR measure owner (QCDR vendor) would still own and maintain the QCDR measure, but would allow other QCDRs to utilize their measure with proper notification. We intended for this policy to help reduce the number of QCDR measures that are similar in concept or clinical topic, or duplicative of other QCDR measures that are being approved. Additionally, in the Quality Payment Program provisions in the CY 2020 PFS final rule (84 FR 63070 through 63073) at § 414.1400(b)(3)(vii), we finalized the QCDR measure rejection criteria considerations. We noted that these considerations would help to ensure that QCDR measures are meaningful and measurable. Although we finalized the QCDR measure rejection criteria, we did not codify that QCDRs may seek permission from another QCDR to use an existing measure that is owned by another QCDR. In order to provide further clarity to the existing policies (82 FR 53813 through 53814; 84 FR 63070 through 63073), we propose to codify a new requirement and add a rejection criterion at § 414.1400(b)(4)(iv)(M) to state, a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. We request comment on this proposal.

(bb) QCDR Not Approved or Not in Good Standing

Additionally, if a QCDR measure owner is not approved or is not in good standing, any QCDR measures associated with that QCDR would also not be approved. We believe it is important to have an approved QCDR measure owner for all approved QCDR measures. This would ensure that there is active involvement by the QCDR measure owner so that any potential measure issues can be mitigated during the specified MIPS performance period. For example, any mid-year guideline changes or measure questions would need to be immediately clarified to avoid negative impacts to clinicians such as the inability to construct a benchmark due to an error in the measure specifications. Therefore, we propose to codify another rejection criterion at § 414.1400(b)(4)(iv)(N) to state that, if a QCDR measure owner is not approved during a given self-nomination period, any associated QCDR measures with that QCDR would also not be approved. We request comment on this proposal.

We have received inquiries from stakeholders on what can be done in circumstances when an active QCDR wishes to use an inactive QCDR's measure. We are interested in feedback from stakeholders on what should be done in such circumstances. For example, what should happen if ''QCDR A'' is using ''QCDR B's'' measures in a given performance period and ''QCDR B'' is terminated mid performance period? Alternatively, what if ''QCDR A'' is using a measure from ''QCDR B'' and ''QCDR B'' decides not to self-nominate for the subsequent performance period? While ''QCDR A'' could partner with ''QCDR B'' as described at § 414.1400(b)(3)(ii), are there other policy options we should consider to minimize impact to the MIPS eligible clinician who has selected the QCDR measure for reporting?

We seek comment on the above circumstances.

(5) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548), CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), and the CY 2021 PFS final rule (85 FR 84930 through 84937) for previously finalized policies for remedial action and termination of third party intermediaries.

In the Quality Payment Program provisions in the CY 2019 PFS final rule

(83 FR 59908 through 59910), we discussed that the threshold for ''inaccurate, unusable or otherwise compromised'' may be met if the submitted data includes TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies that affect more 3 percent of the total number of MIPS eligible clinicians or groups for which data was submitted by the third party intermediary. We are proposing to update the existing language at § 414.1400(f)(3)(ii) to broadly explain that it is up CMS's discretion on whether third party intermediaries' inaccuracies may lead to possible remedial action or termination. As discussed earlier, we propose consolidating and redesignating the existing language at § 414.1400(f) as § 414.1400(e) and § 414.1400(g) as § 414.1400(f) to provide clarity and alignment with the aforementioned proposals to consolidate the duplicative criteria of QCDRs and qualified registries. Therefore, we propose to revise and redesignate existing language at § 414.1400(f)(3)(ii) to proposed § 414.1400(e)(3) to state, contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

i. Public Reporting on the Compare Tools Hosted by the U.S. Department of Health & Human Services (HHS)

In this section of the proposed rule, we propose to amend § 414.1395(c) to add a 1-year delay of publicly reporting new improvement activities and Promoting Interoperability measures and attestations reported via MVP. We also propose a one-time, 1-year delay to subgroup-level public reporting, such that subgroup-level public reporting will begin with CY 2024 performance information available in 2025, and each year thereafter, on the Compare Tools hosted by the U.S. Department of Health and Human Services (HHS), referred to as ''compare tool'' throughout this proposed rule, available at *https://www.medicare.gov/care-compare/* and *data.medicare.gov*, as technically feasible. We are proposing to add facility affiliations, beyond the hospital affiliations currently displayed on individual profile pages. Additional facility affiliations would include: Inpatient rehabilitation facilities (IRFs); long-term care hospitals (LTCHs); skilled nursing facilities (SNFs); inpatient psychiatric facilities (IPFs); home health agencies (HHAs); hospices; and dialysis facilities. Finally, we seek comment on publicly reporting utilization data on clinician and group profile pages.

For previous discussions on public reporting, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2021 PFS final rule (85 FR 84947 through 85 FR 84948) and the Care Compare: Doctors and Clinicians Initiative Page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Compare-DAC*.

(1) MVP and Subgroup Public Reporting

The introduction of MVPs and subgroup reporting provides for new types of performance information that are available for public reporting, provided they meet the established public reporting standards at § 414.1395(b). In consideration of our MVP and subgroup performance information public reporting proposals, we wish to remind readers that all submitted MIPS performance information is available for public reporting (81 FR 77395 through 77397). Additionally, we previously finalized at § 414.1395(c) that, for each program year, CMS does not publicly report any first year measures for the first 2 years, meaning any measure in its first 2 years of use in the quality and cost performance categories. We also note that MIPS performance category and composite final scores for MIPS eligible clinicians participating in MVPs will continue to be publicly reported as required under section 1848(q)(A)(i)(I) of the Act and finalized at § 414.1395(a)(1)(i).

We believe delaying public reporting of certain MVP and subgroup performance information provides a catalyst to encourage clinician participation in MVPs and subgroups while they familiarize themselves with these options. For this reason, we propose, for individuals, groups, and subgroups reporting via MVP, to add a 1-year delay for new improvement activities and Promoting Interoperability measures and attestations, as technically feasible. This means that new improvement activities and Promoting Interoperability measures and attestations would be available for public reporting at their inception in traditional MIPS, but we would delay public reporting of new improvement activities and Promoting Interoperability measures and attestations by 1 year after inception for those reporting via MVP. We note that improvement activities and Promoting Interoperability measures and attestations that have already been in MIPS for more than 1 year and become newly available as part of an MVP would be available for public reporting in the first year the MVP is in the program. That is, non-first year improvement activities and Promoting Interoperability measures and attestations that are newly part of an MVP would be available for public reporting in the first year the MVP is in the program. Table 62 further clarifies when this 1-year delay would apply.

TABLE 62: MVP vs Traditional MIPS: Performance Information Delay Amount

New Improvement Activities and Promoting Interoperability measures and attestations	Delay Amount
Reported via traditional MIPS	No delay; CMS publicly reports new improvement activities and Promoting Interoperability measures and attestations at their inception.
Reported via MVP	CMS does not publicly report the new improvement activities and Promoting Interoperability measures and attestations for the first year.

We recognize that under this proposal, we would be further delaying the release of performance information for improvement activities and Promoting Interoperability measures and attestations reported via MVP. Because of this, as a potential incentive, we also considered whether to delay public reporting of quality and cost

measure information reported via MVP by 1 additional year, for a total of 3 years. We request comments on our proposal to delay public reporting of new improvement activities and Promoting Interoperability measures and attestations reported via MVP by 1 year, as well as any feedback on alternate approaches we should consider spurring clinicians to report performance data on MVPs while making performance data available for patients on the compare tool. We propose to amend this MVP public reporting policy at § 414.1395(c)(2) to state CMS does not publicly report any MVP data on new improvement activities or Promoting Interoperability measure, objective, or activity included in an MVP for the first year in which it is included in the MVP. We also propose to amend § 414.1395(c)(1) to state that CMS does not publicly report any data on new quality or cost measure for the first 2 years in which it is in the program, after which CMS evaluates the measure to determine whether it is suitable for public reporting under § 414.1395(b). Currently, § 414.1395(c) refers to these quality and cost measures as ''first year measures''. We are proposing to change ''first year measures'' to ''new measures''.

The introduction of MVPs and subgroup reporting in MIPS, provides for new types of performance information that are available for public reporting, provided they meet the public reporting standards. Currently, we display information on profile pages at the individual clinician and group level, since this is the level of information we provide for and at which patients and caregivers search for on the compare tool. To ensure that patients and caregivers have access to subgroup performance information, we propose creating a separate workflow from the established ones for individuals and groups, since we only display information at the level at which it was publicly reported. That is, we only publicly report individual-level performance information on individual clinician profile pages and group-level performance information on group profile pages. We do not publicly report group-level performance information on individual profile pages or individual-level information on group profile pages, as doing so would not be truly representative of either the group's or individual's own performance, and we do not want to mislead website users. Instead, we would link from the individual or group profile page to the corresponding subgroup performance information. That is, we propose to create a subgroup public reporting workflow, in which we would indicate with plain language on an individual profile page that the clinician reports performance information as part of a subgroup or on a group profile page that the group has subgroups for purposes of performance information and then link to that subgroup's performance information. Future user testing would determine how to best display and put in plain language subgroup performance information. Subgroup performance information would also be available on *http://data.medicare.gov/*.

Subgroups represent a new type of reporting for MIPS, that is available for clinicians reporting on MVPs or via the APP. For this reason, we also propose to delay all subgroup-level public reporting for 1 year, including measures, activities and attestations across the quality, cost, improvement activities, and Promoting Interoperability performance categories in order to encourage clinician participation in subgroups without the risk of displaying subgroup performance information as clinicians familiarize themselves with the option of subgroup reporting. This would only be a one-time delay in public reporting of subgroup-level information. That is, we would not publicly report any CY 2023 subgroup-level measure, attestation, or activity performance information; this information would be available for public reporting beginning with CY 2024 performance period. We would publicly report PY 2024 subgroup performance information and for each performance year thereafter if the information meets our established public reporting standards. Since we are moving toward more granular level performance information, we believe delaying subgroup public reporting by 1 year provides an incentive for subgroup participation and experience. As an alternative, we also considered a 1-year public reporting delay of performance information for all new subgroups each performance year, as technically feasible. For example, subgroups that begin in CY 2023 are not eligible for public reporting until CY 2024, subgroups that begin in CY 2024 are not eligible for public reporting until CY 2025, and so on for each subsequent year. Another alternative we considered was to publicly report all subgroup performance information without delay and provide new subgroups the opportunity to opt-out, during the preview period, of having their performance information publicly reported for their first year. Some subgroups may want to have their performance information publicly reported and having an overall 1-year delay may be a disincentive to subgroup participation. We seek comment on these considerations. We note that MIPS performance category and composite final scores for MIPS eligible clinicians participating in MVPs will continue to be publicly reported for those participating in subgroups, as required under section 1848(q)(A)(i)(I) of the Act and finalized at § 414.1395(a)(1)(i), and will not be delayed by 1 year for public reporting.

We also seek comment on additional factors that we should consider as we look to expand the availability of MVP and subgroup data on the compare tools. For example, should there be a certain threshold of MVPs available, or clinicians participating in MVPs prior to public reporting? For public reporting of subgroups, are there factors we should consider to make this information usable to the patient but reflective of the subgroups characteristics and composition? Should we test an indicator of MVP participation for compare tool profile pages to see if this is useful information for patients making healthcare decisions? We seek comment on this proposal and additional ways public reporting may encourage MVP participation.

(2) Publicly Reporting APM Performance Pathway Information

In the CY 2021 Quality Payment Program final rule, we finalized to establish an APM performance pathway (APP) beginning in the 2021 MIPS performance year. This is an optional MIPS reporting and scoring pathway for MIPS eligible clinicians who participate in MIPS APMs. We also note that since APP participants are MIPS eligible clinicians, their MIPS performance category and composite final scores will be publicly reported as required under section 1848(q)(A)(i)(I) of the Act and finalized at § 414.1395(a)(1)(i).

In the CY 2017 Quality Payment Program final rule, we finalized, as technically feasible, to use ACO profile pages as a guide to publicly reporting more APM data (81 FR 77398). Currently, groups who participate in an ACO have an indicator showing their participation as well as a link to the ACO profile page with available performance information. User testing has shown that website users find the ACO information meaningful and displayed in a user-friendly way. For this reason, we plan to continue this approach for APM performance information, including that which comes in via the APP, as technically feasible. We also seek comment on

alternative ways to publicly report performance information reporting via APPs and additional considerations to publicly reporting this information.

(3) Facility Affiliations

Compare tool profile pages for clinicians currently provide demographic information, including names, addresses, phone numbers, medical specialties, APM affiliations, Medicare assignment status, board certifications, education and residency, gender, and group and hospital affiliations. User testing consistently shows that Medicare patients and caregivers find value in these types of information. For hospital affiliations, website users have consistently noted the importance of understanding up front the relationships clinicians may have with facilities where they perform services when searching for a clinician. Specifically, patients and caregivers have noted during user testing that hospital affiliation is important to them, since they may be looking for a clinician to perform a procedure at a hospital or want to know the hospitals a clinician could potentially admit them if needed. Linking from the clinician profile page to their affiliated hospital page has provided a seamless experience for patients and caregivers, as they do not need to separately search for clinicians and hospitals; rather, they can navigate to a hospital profile page directly from the clinician's profile page.

With these user testing findings in mind, and because the Compare Tools include information on a number of other types of facilities beyond hospitals, we believe it would benefit patients and caregivers to also be able to navigate from clinician profile pages to profile pages for other types of facilities such as: IRFs; LTCHs; SNFs; IPFs; HHAs; hospices; and dialysis facilities.

Expanding the types of clinician-facility affiliations, beyond hospital affiliation, publicly reported would allow us to provide additional information about clinicians with or without any hospital affiliation but who are affiliated with other types of facilities. User testing with patients and caregivers has shown that facility affiliations not only for hospitals but also for IRFs, LTCHs, SNFs, IPFs, HHAs, hospices, and dialysis facilities would be helpful to their healthcare decision-making. Specifically, we propose adding affiliations to clinician profile pages for each of the following types of facilities, pending the results of user testing, as applicable and technically feasible: IRFs; LTCHs; SNFs; IPFs; HHAs; hospices; and dialysis facilities. User testing will determine how to best display these affiliations on compare tool clinician profile pages. To determine clinician affiliations to these facilities, we would use claims data the same way we do to display the hospital affiliations currently available on clinician profile pages (77 FR 69165). We build the clinician-hospital affiliations based on observing a clinician practicing at a given hospital caring for at least three different Medicare patients on three different dates of service in the preceding 6 months, as documented in Medicare claims. We would use similar criteria for determining additional facility affiliations. Clinicians can email the Quality Payment Program Service Center at *QPP@cms.hhs.gov* if they believe their facility affiliations are displayed incorrectly. We seek comment on the proposal to add affiliations to clinician profile pages for each of the following types of facilities and link to the specific facility's page on the compare tool: IRFs; LTCHs; SNFs; IPFs; HHAs; hospices; and dialysis facilities. Further, we also seek comment on whether there should be a limit on the number of procedures done or conditions treated at a given facility to determine clinician-facility affiliations.

(4) Utilization Data Request for Information

Under section 104(e) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), beginning with 2016, the Secretary is required to integrate utilization data information on Physician Compare.[244] To satisfy section 104(e) of the MACRA, we previously implemented a policy to begin to include utilization data in a downloadable format in late 2017 using the most currently available data, and previously finalized that the specific codes to be included would be determined via data analysis and reported at the eligible clinician level (80 FR 71130). We finalized to continue to include utilization data in the downloadable database (81 FR 77398). This information continues to be available today on *www.data.cms.gov/provider-data*.

To date, we have gathered utilization data for procedures from physician/supplier Medicare Part B non-institutional claims on certain services and procedures and published it in the public use file (PUF) file entitled ''Physician and Other Supplier Data.'' These data are useful to the healthcare industry, healthcare researchers, and other stakeholders who can accurately interpret these data and use them in meaningful analyses. However, this information is presented in a technical way that is not easily accessible or usable by patients, who do not frequently visit *data.cms.gov* or understand medical procedure coding. This information also does not provide detail on the specific conditions clinicians treat, though in select cases it may be inferred by the clinicians and researchers reviewing this information.

Section 10331(b)(3) of the Affordable Care Act requires that for public reporting, to the extent practicable, to include processes to assure that the data made available provides a robust and accurate portrayal of a clinician's performance. In our efforts to continue to provide patients and caregivers with meaningful information to make informed healthcare decisions, we believe utilization data may also have a place on clinician and group profile pages, if presented in a consumer-friendly way. We envision utilization data on patient-facing profile pages providing two main areas of benefit. The first is allowing for more granular clinician searches, so that patients not only find specific types of clinicians but also those clinicians experienced in performing specific types of procedures and/or treating specific conditions. The second is providing categories of utilization data in a more plain language display that is usable to patients and their caregivers. In summary, utilization data could provide information to Medicare patients and their caregivers on the specific diagnoses clinicians treat and the frequency with which certain services or procedures are performed by a clinician or group and/or which types of clinicians do not provide certain services.

For example, someone with severe arthritis of the knee may want to search for an orthopedic surgeon who specifically does knee replacements. The way the clinician search works currently would only show results for ''orthopedic surgeons'' generally. That is, the patient would not see which of these clinicians specialize in this procedure, and likely would need to spend time calling clinicians to ascertain more detail. This could similarly be the case for finding a clinician who focuses on treatment of a certain condition. We believe indicating which clinicians focus on certain procedures or conditions would relieve some of this patient burden, as it would yield more specific search results. There are a number of factors that could influence how procedure- and condition-specific information is

[244] Physician Compare is defined at § 414.1305 as Physician Compare internet website of CMS (or a successor website).

determined, which is why we are seeking comment on this topic in several areas.

For display purposes, we may wish to apply a minimum experience level, such as the number of times a clinician performed a procedure or treated a condition, before a clinician profile is annotated to indicate experience with the condition or procedure. Regarding the methods in which we would identify clinician volume of procedures conducted or treat specific conditions, we would need to set a threshold for making these assertions. We have considered several options. The threshold could be based on the number of times a clinician has performed a procedure or treated a condition within a certain time-period, or the proportion of the clinician's practice that is represented by the procedure or condition. Alternatively, thresholds may be devised based on ranking clinicians compared to their peers (specialty and geography may be considered when defining peers) in volume of procedures performed or frequency with which they treat each condition.

We note too that these approaches utilize Medicare claims data only. That is, these data would not include procedures performed or conditions treated for patients who have other types of insurance, since this information is not available. We also acknowledge that this utilization data only represents the care provided to Medicare beneficiaries and clinicians offer care to those with other forms of insurance. This disclaimer could be added to any data that may be publicly reported. We seek comment on these approaches and whether there are any additional ones we should consider.

Additionally, because the Compare Tools utilize a location-based search, national or local thresholds may be appropriate. For example, clinicians in urban centers may specialize in a small number of procedures that they perform on a weekly basis, while a clinician in a rural area might be the most experienced at a given procedure, but not have comparable volume to the urban clinician who practices a very narrow scope. We seek comment on these considerations as well as if there are others.

We also seek comment on the potential types of utilization data that, if publicly reported, could help Medicare patients and their caregivers make informed healthcare decisions, as well as on technical considerations for presenting a specific affiliation between clinicians and diagnoses and/or procedures. Specifically, we seek comment on:

- The types of conditions and procedures that would most benefit patients' clinician searches;
- Important features and considerations for clinician searches by conditions or procedures;
- The lookback period for Medicare claims in order to identify a clinician's volume of procedures balancing frequency with recent experience (for example, 6 months, 1 year, 2 years);
- Clinician specialties or conditions with special considerations (for example, non-patient facing clinicians);
- The maximum number of conditions treated or procedures performed to display on a given clinicians profile page; and
- Methods to set a threshold of treatment volume to display that a clinician commonly performs a procedure or treats a condition. For example, the threshold could be: (1) The number of times a clinician treated a condition or performed a procedure; (2) the total scope that a condition or treatment represents in a clinician's practice; or (3) the clinician's rank—either overall among all clinicians or among a subset of clinicians—in the number of times that clinician treated a condition or performed a procedure.
- Any other factors or considerations not listed above.

4. Overview of the APM Incentive

(a) Overview

Under the Quality Payment Program, eligible clinicians who are Qualifying APM Participants (QPs) for a year are eligible to receive an APM Incentive Payment in the corresponding payment year for payment years 2019 through 2024. In the CY 2017 Quality Payment Program final rule (81 FR 77480 through 77489), we finalized at § 414.1450(d) that this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2021 payment will correspond to the 2019 performance year), and at § 414.1450(b)(1) that the payment is equal to 5 percent of the estimated aggregate payments for covered professional services in the base period (the year between the QP performance and payment years).

We also finalized at § 414.1450(c)(1) (82 FR 31729) that the APM Incentive Payment would go to the TIN associated with the Advanced APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. In 2019, our first year of making APM Incentive Payments, we learned that the amount of time between the QP Performance Period (during which QP status is attained) and the QP payment year (during which APM Incentive Payments are issued) creates challenges to disbursing the payment for some QPs in a routine and efficient manner. Consistent with section 1833(z) of the Act, QP status is determined for, and connected to, an eligible clinician (identified by their NPI) for the QP payment year based on their Advanced APM participation during the QP Performance Period. We do not believe that changes in a QP's practice or TIN in the interim year between the QP determination and the QP payment year should affect a QP's ability to receive the APM Incentive Payment. To address some of the unanticipated challenges we encountered in disbursing the APM Incentive Payments, in the CY 2021 PFS final rule, we finalized a hierarchy, codified at § 414.1450, that, based on our experience and lessons learned in making payments in 2019, would provide more ways to identify an appropriate TIN to which we can make the APM Incentive Payment when a QP has experienced changes in their practice or TIN since the performance year in which they attained QP status.

(c) APM Incentive Payment Recipient

In the 2021 PFS final rule (85 FR 84472), we revised our approach to identifying the TIN or TINs to which we make the APM Incentive Payment, and established a process that enables QPs to provide CMS with updated enrollment information that could be used to complete the payment in the event our approach does not yield an appropriate TIN or TINs. The process for those QPs to update their information, as well as a preliminary list of NPIs to whom it may be applicable, is included in a Public Notice published annually in the **Federal Register**. We explained in the CY 2021 PFS final rule that the revised approach would involve looking at a QP's relationship with TINs at different, specified periods in time, as well as considering the relationships such TINs have with certain APM Entities and Advanced APMs. We stated that we believe this revised approach enables us to more appropriately identify TINs with which QPs currently have relationships to receive other Medicare payments, and through which the QPs likely would anticipate receiving their APM Incentive Payments. We noted that, when the QP is no longer affiliated with the TIN through which they achieved QP status, this approach would prioritize identifying an alternate TIN with which the QP is affiliated at the time the APM Incentive Payment is made, and to which it would be appropriate to make the payment. The approach we adopted

also serves to reduce uncertainty for QPs as they anticipate their APM Incentive Payments, as well as potential delays in our ability to make their payments.

To improve and expand the ways we identify the TIN(s) to which we make the APM Incentive Payment for a QP in a timely and efficient manner, we finalized a policy to sequentially apply a decision hierarchy and codified the hierarchy in § 414.1450(c). We apply the hierarchy by beginning at the first step, and if we are unable to identify one or more TINs with which the QP has a current affiliation at this step, we move to the next and successive steps of the hierarchy until we do identify one or more TINs with which the QP is affiliated.

As discussed in the CY 2021 PFS final rule, if we identify more than one TIN at the applicable step in the hierarchy, we divide the APM Incentive Payment proportionally between the QP's TINs based on the relative paid amount for Part B covered professional services that are billed through each of the TINs. We propose to clarify that, when we divide the APM incentive payment between two or more TINs, we apportion the APM incentive payment among TINs based on the share of total payments for covered professional services made to each TIN in the same base year that we use to calculate the APM incentive payment for the year. To calculate the APM incentive payment, we sum the total estimated aggregate payments for covered professional services for a QP for the base year, which is based on claims submitted for covered professional services, as codified at § 414.1450(b)(1) through (3). We propose to codify this policy at § 414.1450(c).

In the course of making APM Incentive Payments during CY 2020 PFS final rule, we explored the possibility of expanding our search at each step of the hierarchy at § 414.450(c) to identify potential payee TINs that are associated with the QP during the QP payment year. Based on our findings, we believe expanding our search in this way would enable us to make payments earlier in the calendar year and reduce the number of QP NPIs for whom we cannot identify a payee TIN using our hierarchy, and thus, rely on our Public Notice to request additional information. Therefore, we now propose to revise the hierarchy at § 414.1450(c) so that, using the criterion described in each step of our current regulation, we would first seek to identify a TIN associated with the QP during the base year, and if no such TIN is identified in the base year, we would then seek to identify a TIN associated with the QP during the payment year. We have found in many instances that there are changes in enrollment information in PECOS for a QP over the span of 2 years between the QP performance period and payment year. By using enrollment information for the QP during the payment year, we are more likely to identify an appropriate TIN to which to make the APM incentive payment hierarchy. Under the proposal, applying the steps in the APM incentive payment hierarchy, we would make the APM Incentive Payment to one or more solvent TINs associated with the QP, identified by paid Medicare Part B claims for covered professional services and associated PECOS enrollment information during the base period, and if no such TIN is identified, we would make the payment to such TINs associated with QP during the payment year, according to this section. If no such TIN or TINs can be identified at a particular step, we would move to the next and successive steps listed in § 414.1450(c)(1) through (8) until we identify one or more solvent TIN or TINs with which the QP is associated, and then would make the APM Incentive Payment to any such TIN(s). If more than one TIN is identified at a step based on paid claims during the applicable year, either the base year or payment year, as we explain earlier and propose to codify in the regulation under § 414.1450(c), we divide the APM Incentive Payment proportionately among such TINs according to the relative total paid amounts for Part B covered professional services to each TIN in same the base year we use to calculate the APM incentive payment.

We propose, for each step in the APM incentive payment decision hierarchy, we would first search for a payment TIN or TINs associated with the QP during the base period., If no such TIN is found during the base year, we would search for any TIN or TINs that are similarly situated with respect to the criterion at that step in the hierarchy and associated with the QP during the payment year. If such a TIN or TINs are found, we would make the APM incentive payment to such TIN or TINs. We would continue at each step in the hierarchy to first attempt to identify the relevant base year TIN or TINs associated with the QP because we believe such TINs are more likely to be associated with the APM Entity through which the QP attained their QP status during the QP performance period. However, if no such TIN is found in the base year, we would proceed at that step to search for a TIN or TINs with which the QP is associated in the payment year.

We believe this approach creates the greatest opportunity to identify and pay an appropriate TIN as efficiently and early as possible during the payment year. The proposed change would maintain the current hierarchy while adding a sub-step at each level in which we would conduct our search based on more current enrollment information. The proposed change would allow for the identification of an appropriate TIN or TINs at each step by first checking the base year, and then checking the payment year before moving on to the next step in the process. We believe that by maintaining the current hierarchy we would continue to incent Advanced APM participation by prioritizing making payments to TINs affiliated with Advanced APMs, even if they are not in the same Advanced APM Entity through which QP status originally was achieved. For example, we anticipate that many eligible clinicians who earned QP status in 2020 through a practice participating in the CPC+ model would join the new Primary Care First (PCF) model in 2022.

In the event the eligible clinician's CPC+ participant TIN is no longer active, our proposed modification to the hierarchy would enable us to pay the APM Incentive Payment to a TIN participating in the PCF model in 2022. We continue to believe it would be appropriate to first identify the relevant base year TIN or TINs at each step in of the hierarchy because we believe those TINs are more likely to be associated with the APM Entity through which the QP attained their QP status during the QPs performance period. However, if no TIN is found in the base year, we would proceed to identify any TINs associated with the QP in the payment year; and then use the same process for the subsequent steps in the hierarchy until we identify one or more TINs associated with the QP at a particular step for a particular year (base year or payment year). We believe this approach will be a more efficient and expeditious way to identify a TIN or TINs to which to make the APM incentive payment for QPs.

We seek comment on this proposal to amend our APM Incentive Payment decision hierarchy to include an additional attempt to identify and pay, at each step, one or more solvent TINs associated with the QP during the payment year when no such TIN is identified for the QP in the base year.

c. Advanced APMs

1. Qualifying APM Participant Determination

a. General Overview:

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy at § 414.1425(b) for Qualifying APM Participant (QP) determinations. For the purposes of making QP determinations, an eligible clinician must be present on the Participation List of an APM Entity in an Advanced APM on one of the ''snapshot dates'' (March 31, June 30, or August 31) for the QP Performance Period. An eligible clinician included on a Participation List on any one of such dates is included in the APM Entity group even if that eligible clinician is not included on that Participation List at one of the prior- or later-listed dates. We perform QP determinations for the eligible clinicians in an APM entity group three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations at the APM Entity group level based on participation in the Advanced APM. For eligible clinicians who appear on a Participation List in more than one APM Entity, but do not to achieve QP status based on any APM Entity level determinations, we make QP determinations at the individual level as described in § 414.1425(c)(4). Likewise, for eligible clinicians on an Affiliated Practitioner list for an Advanced APM we make QP determinations at the individual level three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates as described in § 414.1425(b)(2).

b. QP thresholds and Partial QP thresholds

Section 1833(z)(2)(B) of the Act describes the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, is applicable beginning in the payment year 2019. The All-Payer Combination Option, which uses the Medicare Option, as well as an eligible clinician's participation in Other Payer Advanced APMs, is applicable beginning in the payment year 2021. In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439) we finalized our policy for the Medicare Option as codified at § 414.1430(a) and the All-Payer Option at § 414.1430(b).

Section 114 of division CC of the CCA amended section 1833(z)(2)(B) of the Act with regard to payment years 2023 and 2024 (which correspond respectively to performance years 2021 and 2022), specifically by freezing for such years the applicable payment amount and patient count thresholds used to make determine an eligible clinician's QP determinations status. Specifically, the CAA amended section 1833(z)(2)(B) of the Act to continue the QP payment amount thresholds that apply in payment years 2021 and 2022 to payment years 2023 and 2024. Additionally, the CAA, 2021 amended section 1833(z)(2)(D) of the Act to require that, for payment years 2023 and 2024, the Secretary use the same percentage criteria for the QP patient count threshold that are applied in payment year 2022. As such, the Medicare Option QP thresholds payment years 2023 and 2024 (for performance years 2021 and 2022) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The CAA also amended section 1848(q)(1)(C)(iii) of the Act to extend the Partial QP thresholds that are established for payment years 2021 and 2022 through payment year 2024. Therefore, the Partial QP thresholds for payment years 2023 and 2024 (performance years 2021 and 2022) will remain at 40 percent for the payment amount method and 25 percent for the patient count method. For performance years beginning with 2023 (corresponding to payment years beginning with 2025) the statute prescribes the QP thresholds for the payment amount method, and the QP thresholds we established for the patient count method at § 414.1430 will take effect. Specifically, for performance years beginning with 2023, the Medicare Option QP thresholds will be 75 percent for the payment amount method and 50 percent for the patient count method. The Partial QP thresholds under the Medicare Option will be 50 percent for the payment amount method and 35 percent for the patient count method.

Under the All-Payer Combination Option, the QP thresholds for performance years 2021 and 2022 (corresponding to payment years 2023 and 2024) will be 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for performance years 2021 and 2022 will be 40 percent for the payment amount method and 25 percent for the patient count method. In order to become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain threshold percentages under the Medicare Option. For performance years 2021 and later (corresponding to payment year 2023 and later), the minimum Medicare Option threshold an eligible clinician must meet for the All-Payer Combination Option is 25 percent for the payment amount method or 20 percent under the patient count method.

TABLE 63: QP Threshold Score Updates

Medicare Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Payment Amount Threshold	50		50		75	
Partial QP Payment Amount Threshold	40		40		50	
Medicare Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35		35		50	
Partial QP Patient Count Threshold	25		25		35	
All-Payer Combination Option - Payment Amount Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	50	25	50	25	75	25
Partial QP Patient Count Threshold	40	20	40	20	50	20
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum
All-Payer Combination Option - Patient Count Method						
Performance year / Payment Year	2021/2023 (Percent)		2022/2024 (Percent)		2023/2025 and later (Percent)	
QP Patient Count Threshold	35	20	35	20	50	20
Partial QP Patient Count Threshold	25	10	25	10	35	10
	Total	Medicare Minimum	Total	Medicare Minimum	Total	Medicare Minimum

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of OMB's implementing regulations. To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 64 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

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TABLE 64: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Administrative Support Worker	43-9000	18.41	18.41	36.82
Anesthesiologists	29-1211	130.50	130.50	261.00
Billing and Posting Clerks	43-3021	20.01	20.01	40.02
Bookkeeping, Accounting, and Auditing Clerks	43-3031	21.20	21.20	42.40
Computer System Analysts	15-1211	47.61	47.61	95.22
Family Medicine Physicians	29-1215	103.06	103.06	206.12
General Internal Medicine Physicians	29-1216	101.42	101.42	202.84
Licensed Practical and Licensed Vocational Nurses	29-2061	24.08	24.08	48.16
Medical and Health Services Managers	11-9111	57.12	57.12	114.24
Obstetricians and Gynecologists	29-1218	114.96	114.96	229.92
Office and Administrative Support Workers, All Other	43-9199	18.91	18.91	37.82
Pediatricians, General	29-1221	88.74	88.74	177.48
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	105.22	105.22	210.44
Psychiatrists	29-1223	104.38	104.38	208.76
Secretaries and Administrative Assistants	43-6014	19.43	19.43	38.86
Surgeons, Except Ophthalmologists	29-1248	120.99	120.99	241.98

For the CY 2019 and CY 2020 PFS final rules, we used the BLS wage for ''Physicians and Surgeons'' (occupation code 29–1060) to estimate the cost for Physicians. In BLS' most recent set of occupational wage rates (dated May 2020) they have discontinued this occupation in their wage data. As a result, in order to estimate the burden for Physicians, we are using a rate of $217.32/hr which is the average of the following BLS occupations and adjusted wage estimates.

TABLE 65: Physician Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	130.50	130.50	261.00
Family Medicine Physicians	29-1215	103.06	103.06	206.12
General Internal Medicine Physicians	29-1216	101.42	101.42	202.84
Obstetricians and Gynecologists	29-1218	114.96	114.96	229.92
Pediatricians, General	29-1221	88.74	88.74	177.48
Physicians, All Other; Ophthalmologists, Except Pediatric	29-1228	105.22	105.22	210.44
Psychiatrists	29-1223	104.38	104.38	208.76
Surgeons, Except Ophthalmologists	29-1248	120.99	120.99	241.98
Total				1,738.54
Average Wage (1,738.54/8)				217.32

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As indicated, we BLS' hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.806)

Pending our finalization of the following provisions, the proposed changes will be subject to the standard PRA process under OMB control number 0938–0921 (CMS–10110). The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices that will provide the public with opportunities for public review and comment. We expect to publish the 60-day notice shortly after the publication of the CMS–1751–F final rule.

The new provisions at §§ 414.802 and 414.806 would implement new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021 (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 401''), which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Specifically, to implement the new reporting requirements for manufacturers without Medicaid drug rebate agreements, we are proposing to modify: (1) The definition of drug at § 414.802; and (2) the regulations describing civil money penalties at § 414.806. The new requirements will improve the accuracy of reported payment limits and limit the use of WAC-based pricing.

For the purposes of section 401's new reporting requirements, for manufacturers without Medicaid drug rebate agreements, confidentiality requirements appear in section 1847A(f)(2)(D) of the Act which states that the ASP data are confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler or prices charged for drugs or biologicals by such manufacturer or wholesaler, except—as the Secretary determines to be necessary to carry out this section (including the determination and implementation of the payment amount), or to carry out section 1847B of the Act; to permit the Comptroller General of the United States to review the information provided; to permit the Director of the Congressional Budget Office to review the information provided; to permit the Medicare Payment Advisory Commission to review the information provided; and to permit the Medicaid and CHIP Payment and Access Commission to review the information provided.

For manufacturers with Medicaid drug rebate agreements, confidentiality requirements appear in section 1927(b)(3)(D) of the Act which states that the ASP data are confidential and shall not be disclosed by the Secretary in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—as the Secretary determines to be necessary to carry out this section, to permit the Comptroller General to review the information provided, and to permit the Director of the Congressional Budget Office to review the information provided.

The burden associated with these requirements is the time and effort required by manufacturers of drugs and biologicals payable under Medicare Part B to prepare and submit the required ASP data to CMS. We have previously estimated the burden associated with ASP reporting requirements for manufacturers with Medicaid drug rebate agreements. Because section 401 extends the ASP reporting requirements to manufacturers without Medicaid drug rebate agreements, we are updating our burden estimates to account for the additional manufacturers who will now be required to report ASP data to us.

As described in section III.D.1. of this proposed rule, in considering whether to exclude repackagers from the reporting requirements at section 1847A(f)(2) of the Act, we conducted analyses to estimate: (1) The proportion of repackaged products in our existing ASP data; (2) the number of new ASP submissions we can expect as a result of the new reporting requirements under section 401; and (3) the proportion of those (new) submissions that involve repackaged products.

Based on our existing ASP data, 547 manufacturers (respondents) report ASP data to us. Of these, 331 respondents have products for which they are required to submit ASP data, and 216 respondents have products for which they currently submit ASP data voluntarily, but will now be required to do so under section 1847A(f)(2) of the Act. (331 + 216 = 547)

We also estimate that under the new reporting requirements of section 401, a total of 568 respondents have products for which they will now be required to report ASP data to us. The 568 includes the 216 respondents (above) and 361 respondents who have products (identified by us) for which they will now be required to submit ASP data under section 1847A(f)(2) of the Act and did not previously voluntarily submit these data to us. There were 9 respondents who voluntarily submitted ASP data for some, but not all, of their products identified in our analysis. (216 + 361 − 9 overlap = 568)

We estimate a total of 740 respondents will report ASP data to us. This includes the 547 respondents who currently submit ASP data to us (voluntarily, or as currently required), and the 361 respondents who have products (identified by us) for which they will now be required to submit ASP data under section 1847A(f)(2) of the Act and did not previously voluntarily submit these data to us. However, there were 168 respondents who currently are required to submit ASP data to us, or who voluntarily submit ASP data to us, for whom we identified additional products that they did not previously submit ASP data, and will now be required to submit ASP data for these additional products under the new reporting requirements of section 401. (547 + 361 − 168 overlap = 740)

These respondents submit ASP data four times per year for a total of 2,960 submissions (740 respondents × 4 submissions/year).

Based on our experience with ASP data reporting, we continue to estimate that the time associated with reporting, record keeping, and third-party disclosure for ASP data reporting is 13 hours: 10 hours to review instructions and search existing data resources and 3 hours to gather the data, compile the data, submit via electronic media and upload to the automated system. This estimate includes labor costs for respondents to extract data from their information systems and to compile and submit the ASP data, including signature, to CMS via the internet-based automated system and electronic media. This estimate also includes the cost of the compact disc (CD) and overnight mail service used to report the data, time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

Based on these analyses and assumptions, we estimate an annual burden of 38,480 hours (2,960 submissions/yr × 13 hours per response) at a cost of $1,495,332.80 (38,480 hr × $38.86/hr), rounding to $1,495,333.

TABLE 66: Annual Requirements and Burden for Requiring Certain Manufacturers to Report Drug Pricing Information for Part B

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802, 414.806 (Requiring Certain Manufacturers to Report Drug Pricing Information for Part B)	0938-0921	740	2,960	13	38,480	38.86	1,495,333

We welcome comment on the likely costs or savings manufacturers from this provision.

2. ICRs Regarding the Medicare Shared Savings Program (Sections VII.F.8.a. and b.)

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to sections VII.F.8.a. and b. of this proposed rule for a discussion of the impacts associated with this rule's proposed changes to the Shared Savings Program's quality reporting requirements, beneficiary assignment methodology, repayment mechanism requirements, requirements for disclosure of prior participation in the Shared Savings Program by the ACO, ACO participants, and ACO providers/suppliers, requirements for ACOs to submit sample ACO participant agreements and executed ACO participant agreements to CMS, and beneficiary notification requirements.

3. ICRs Regarding the Medicare Ground Ambulance Data Collection System (§ 414.626)

Section 1834(l)(17) of the Act requires that the Secretary develop a ground ambulance data collection system that collects cost, revenue, utilization, and other information determined appropriate by the Secretary with respect to providers of services and suppliers of ground ambulance services (ground ambulance organizations). Section 1834(l)(17)(I) of the Act states that the PRA does not apply to the collection of information required under section 1834(l)(17) of the Act. Accordingly, this collection of information section does not set out any burden for the proposed provisions. Please see section VII. of this preamble for a discussion of the estimated impacts.

4. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model (§§ 410.79, 414.84, 424.205, and 424.502)

In section III.L. of this proposed rule, we propose policies necessary to shorten the Medicare Diabetes Prevention Program (MDPP) services period to one (1) year on a prospective basis, amend and update the amount of the performance payments for the Core Sessions and Core Maintenance Sessions, and make changes to eliminate the ongoing maintenance phase for MDPP beneficiaries who start MDPP set of services on or after January 1, 2022. In addition, we propose to add a provision to waive the provider enrollment Medicare application fee for all organizations enrolling in Medicare as MDPP suppliers during the MDPP expanded model. We expect the proposed policies will increase the number of eligible organizations willing to enroll as MDPP suppliers. We also anticipate that the shortened service period will make MDPP more marketable to beneficiaries in that their time commitment is reduced and less intimidating with a 12-month vs 24-month service period. We anticipate the shortened MDPP services period will reduce the recordkeeping burden for suppliers. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA. Accordingly, this collection of information section does not set out any burden for the proposed provisions. Please see section VII. of this preamble for a discussion of the estimated impacts.

5. ICRs for Prepayment and Post-payment Definitions, Documentation Request Timeframes, and Payment Denials for Noncompliance with Documentation Requests (§§ 405.902, 405.903, 405.929, and 405.930)

In section III.N.2. of this proposed rule, we are proposing to: (1) Define key terms including ''additional documentation,'' ''additional documentation request,'' ''post-payment medical review,'' and ''prepayment medical review;'' (2) codify contractors' authority to request additional documentation for prepayment and post-payment review within established timeframes; (3) codify timeframes for response to requests for documentation; (4) codify result of a failure to comply with prepayment or post-payment documentation request(s) by a provider or supplier, specifically denial of payment.

The codification of contractor authority to request additional documentation for post-payment reviews, associated timeframes, and resulting denials for failure to comply with these requests is not subject to the PRA per 5 CFR 1320.3(h)(9). The request for additional documentation would be on a case-by-case basis using non-standardized follow-up questions.

With regard to the (1) definitions for ''additional documentation'' and ''additional documentation request,'' ''post-payment medical review,'' and ''prepayment medical review;'' (2) the codification of contractor authority to request additional documentation for pre-payment reviews; (3) the associated provider and supplier timeframes for providing additional documentation from the pre-payment reviews; and (4) possible denials for failure to comply with these requests, we do not expect that these proposals, if finalized, would affect our information collection burden estimates because these policies do not require providers or suppliers to submit any more documentation to CMS than what is already approved by OMB under control number 0938–0969 (CMS–10417). The proposed regulations simply codify certain requirements by clarifying definitions, timeframes, and results for noncompliance.

6. ICRs Regarding the Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (§ 423.160(a))

Pending our finalization of the following provisions, the proposed changes will be subject to the standard PRA process under OMB control number 0938–1396 (CMS–10755) to give

stakeholders optimal opportunity to comment on our proposed burden for this provision, given how dynamic the burden for EPCS is. The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices that will provide the public with opportunities for public review and comment. We expect to publish the 60-day notice shortly after the publication of the final rule.

The purpose of this proposal is to continue to implement section 2003 of the SUPPORT for Patients and Communities Act, which requires that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. We refer readers to the CY 2021 PFS final rule (85 FR 84472) for our previously finalized requirements and burden for the first phase of implementing this statutory mandate, which required prescribers to use the NCPDP SCRIPT 2017071 standard for Electronic Prescription for Controlled Substances (EPCS) prescription transmissions. The purpose of this proposed rule is to propose delaying the date for CMS to begin taking compliance actions, proposing certain exceptions to the mandate, and proposing a compliance threshold.

In the CY 2021 PFS final rule, we estimated that the one-time burden to implement this provision would be 828,750 hours (165,750 prescribers * 6 hr) at a cost of $36,418,590 (994,500 hr * $36.62/hr). We arrived at the estimate of 165,750 prescribers having to implement EPCS based on taking the 425,000 Part D prescriber practices, and decreasing that amount by 60 percent to account for the 60 percent of prescriber practices that likely already had EPCS in place by January 1, 2021. Based on our current PDE data, we estimate that 70 percent of Part D prescribers already conduct EPCS,[245] which would leave 30 percent of Part D prescribers that would have to implement EPCS, if we did not propose any exceptions to this mandate. We also propose that long term care facilities will have an extension until January 1, 2025 along with the following exceptions to the EPCS mandate: (1) For prescriptions issued when the prescriber and dispensing pharmacy are the same entity; (2) cases where prescribers issue only a small number of Part D; (3) cases where a prescriber's NCPDP database address is in a geographic service area of an emergency or disaster declared by a federal, state or local government entity; and (4) cases where a prescriber has received a CMS-approved waiver. These exceptions will result in fewer prescribers being required to conduct EPCS.

Based on our PDE data, we believe that these exceptions will substantially decrease the number of prescribers having to implement EPCS as a result of this regulation. We have listed the exceptions and the estimated number of prescribers falling under each exception in the Table 67.[246] We do not anticipate that our proposal to include a compliance threshold of 70 percent will have any material impact on the impact of this provision. The reason for this is that based on our PDE data and conversations with prescribers, we believe that the 30 percent or less of the time that prescribers are not e-prescribing is because they are unable to e-prescribe, so they would have applied for a waiver. Although there are sometimes scenarios where beneficiaries may request that their prescriptions not be transmitted electronically, it appears as though those circumstances are not enough to make a material impact, since beneficiaries often change their views when they are given countervailing reasons that the prescriptions should be transmitted via EPCS.

TABLE 67: Number of Affected Prescribers by Exception Type

Exception	Estimated Number of Impacted Prescribers*
Cases where the Practitioner and Dispensing Pharmacy Are the Same Entity	75,927
Prescribers who Prescribe fewer than 100 Part D controlled substance prescriptions per year	470,000
Cases where Prescriber is in a Disaster or Emergency Area	30,964
Cases where Prescriber Applies for a Waiver	100
Individuals in Long Term Care Facilities	5,773
Total Number of Impacted Prescribers	582,764

* This information is based on PDE data pulled on April 6, 2021.

Table 67 gives our estimate of the number of prescribers affected by our proposed exceptions broken down by the type of exception. As shown in Table 67, we estimate that our exceptions will exempt approximately 582,664 prescribers from the EPCS requirement, which consistutes approximately 38 percent of prescribers, since there are an estimated 1,548,221 Part D prescribers [247] (582,664/1,548,221). Since the number of exempted prescribers from this mandate far exceeds the number of prescribers who currently do not e-prescribe controlled substances in Part D, we do not expect that the total number of Part D prescribers who electronically prescribe controlled substances will increase following our implementation of this mandate. As a result, we do not believe there will be a measurable impact to the prescriber community as a whole, should this provision be finalized, as proposed.

However, for individual prescribers who have to implement this mandate,

[245] This information is based on PDE data pulled on April 6, 2021.

[246] This information is based on PDE data pulled on April 6, 2021.

[247] This information is based on PDE data pulled on April 6, 2021.

we expect that the implementation costs will be the same amounts that we finalized in the CY 2021 PFS final rule. Based on the modeling that we have seen, we have found that EHR companies provide the initial set-up of e-prescribing software free of charge, provided the prescribers pay the per transaction cost of $1.88 mentioned in the CY 2021 PFS final rule. Based on the comments received on our CY2021 PFS proposed rule, we understand that implementing EPCS can lead to technological glitches, and then fixing those issues. We understand that the EHR companies remedy the issues free of charge. However, we also understand that such fixes take time away from the medical office staff. We estimate that such fixes would take the staff approximately 1 extra hour from the estimate given in our CY 2020 PFS proposed rule, when averaged across all prescribers. As a result, we have changed our one-time burden estimate of e-prescribing set-up from 5 hours to 6 hours per provider, which means a total of 994,500 hours (165,750 prescribers * 6 hr) at a cost of $36,617,490 (994,500 hr * $36.82/hr), since we anticipate that this work would be completed by an Administrative Support Worker. In this regard, the impact of this rule is plus 1 hour per response, plus 165,750 hours (165,750 prescribers × 1 hr/response), and $6,102,915 (165,750 hr * $36.82/hr).

We have proposed that prescribers have the ability to apply for a waiver from the EPCS requirement, should they be facing circumstances beyond their control that prevent them from e-prescribing, and these circumstances are not the result of a natural disaster or public health emergency. Due to the high prevalence of EPCS, the miniscule compliance actions that we are proposing for non-compliance, and the number of prescribers that we expect to exempt from the mandate, we only expect to receive about 100 attestations per year. Although we proposed certain fields be in this attestation, these were minimal, and there was no accompanying documentation required. (Note, as outlined in section II.Q. of this final rule, to meet the standard for a waiver, prescribers must provide documentation showing the existence of a circumstance beyond their control and that such a circumstance prevents them from conducting EPCS.) We expect that each attestation would take 10 minutes (0.1667 hr) for a prescriber at $210.44/hr to complete. In aggregate, CMS estimates an annual burden for filling out attestations of 16.67 hours (100 attestations × 0.1667 hr) at a cost of $3,508.04 (16.67 hr × $210.44/hr). In addition, we solicit comment on any other potential information collection implications.

TABLE 68: Burden for Electronic Prescribing of Controlled Substances Requirement

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan)	0938-1396	100	100	0.1667	16.67 hours	210.44	3,508.04

7. ICRs Regarding Open Payments Proposals Included in the CY 2022 PFS (42 CFR Part 403)

The following requirement and burden changes will be submitted to OMB for approval under control number 0938–1237 (CMS–10495). The following estimates burden changes to the Open Payments final rule at §§ 403.900 through 403.914 as proposed by this proposed rule.

a. Payment Context Field for Teaching Hospitals

The proposed mandatory context field is a new requirement for reporting entities submitting and attesting to records that are attributed to teaching hospitals only. The field will be freeform text entry. We estimate that for each applicable manufacturer and applicable group purchasing organization (GPO), the inclusion of this field for collection and reporting activities will average an additional 6 total hours. The applicable instrument for these activities in the current PRA package is the ''General-Research-Ownership Submission Data Elements''. At the support staff cost per FTE of $42.40/hr, this would increase costs by $254.40 (6 hr × $42.40/hr) per applicable manufacturer or applicable GPO submitting teaching hospital records. However, because we anticipate fewer disputes due to this proposed field, we believe it will decrease dispute resolution by 2 total hours for support staff at $42.40/hr respectively, reducing costs by $84.80 (2 hr × $42.40/hr) per applicable manufacturer and applicable GPO. This results in a net increase in burden for each applicable manufacturer and applicable GPO submitting teaching hospital records of $169.60 ($254.40 − $84.80). In Program Year (PY) 2019, 794 applicable manufacturers and applicable GPOs submitted at least one teaching hospital record, meaning the increase in burden will be a total of 3,176 hours (4 hours × 794 reporting entities) at a cost of $42.40/hr or a total of $134,662.40 (3,176 × $42.40).

In addition, we estimate this proposal would reduce teaching hospital dispute resolution estimates by 2 hours per support staff FTE at $37.82/hr or $75.64 (2 hr × $37.82/hr) per teaching hospital with records attributed to them. In PY 2019, 1,202 hospitals had record attributed to them, so for teaching hospitals we estimate a total burden reduction of 2,404 hours at a cost of $90,919.28 (2,404 × $75.64).

In aggregate, we estimate an annual burden of 772 hours (3,176 − 2,404) at a cost of $43,743.12 ($134,662.40 − $90,919.28).

b. Optional Annual Recertification

The annual recertification is voluntary for applicable manufacturers or applicable group purchasing organizations. We approximate that 15 percent of applicable manufacturers and group purchasing organizations, or 240 reporting entities (0.15 [1,595 applicable manufacturers and applicable GPOs]) will complete and submit the proposed optional annual recertification. We anticipate that it will be a simple check box form to be included in the AM (Attestation) and GPO (Attestation) Annual IC Requirement and the ''Attestation and Assumptions Screen Shots'' Instrument in the existing PRA

package. We estimate that it would take 0.5 hours at $42.40/hr for support staff to complete and submit the recertification. In aggregate, we estimate an added annual burden of 120 hours (240 entities × 0.5 hr/response) at a cost of $5,088 (120 hr × $42.40/hr).

c. Defining a Physician-Owned Distributorship (42 CFR 403.902)

The proposed new definition is not subject to the PRA since it would not revise, add, or remove any collection of information requirements or burden.

d. Disallowing Record Deletion Without Reason (§ 403.904(a)(3))

This proposal clarifies that entities are not permitted to delete records without reason once their timeliness, completeness, and accuracy has been attested to. In order to ensure compliance with this requirement, a freeform text dialogue box will be added to the system when records are deleted that asks the applicable manufacturer or GPO to input a reason for the deletion. This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the ''Open Payments User Guide'' Instrument in the existing PRA package. We anticipate that this would take an average of 2 hours at $42.40/hr to input a reason for the deletion. In aggregate, we estimate an added annual burden of 80 hours (40 applicable manufacturers or GPOs deleting records annually × 2 hr/response) at a cost of $3,392 (80 hr * $42.40/hr).

e. Disallow Publication Delays of General Payments

A very small number of general payments are delayed from publication by reporting entities every year, and these records will simply either be reported as research records instead, or not delayed at all. Therefore, we anticipate a negligible burden for this proposal.

f. Short Term Loans (§ 403.902)

This proposal is merely a clarification of an existing requirement in regulation text. The purpose of this language is to clarify that the exemption for short-term loans from reporting requirements only applies for loans of less than 91 cumulative days per calendar year. In other words, multiple short-term loans in a calendar year would still meet reporting requirements if they add up to 91 days or greater. We do not believe this proposal will change reporting behavior, and therefore do not anticipate an increase in burden.

g. Remove General Ownership Records

Currently the Open Payments system allows for a reporting entity to submit either a general record with a nature of payment category of ownership, or an ownership and investment interest record. For Program Years 2015–2019, approximately 92 applicable manufacturers and GPOs reported records with the nature of payment category of ownership. Since reporting these general records as ownership records will require the addition of two additional pieces of information, we anticipate that it will take these 92 entities an additional 3 hours at $42.40/hr to report the two extra fields. In aggregate, we estimate an added annual burden of 276 hours (92 entities × 3 hr/response) at a cost of $11,702 (276 hr × $42.40/hr). This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the ''Open Payments User Guide'' Instrument in the existing PRA package.

h. Updated Contact Information (§ 403.908(c)(3))

This proposal creates a requirement for reporting entities to keep their contact information up to date with CMS. The ability to communicate with a reporting entity is important because CMS may need to contact the entity in the case of perceived issues with the records. Applicable manufacturers and applicable GPOs will only be required to update their contact information if the two contacts provided become obsolete due to a change in the organization. This will also only apply to entities that do not have records to report for 2 years after a program year in which they reported. Therefore, we anticipate that it will only affect approximately 30 applicable manufacturers and applicable group purchasing organizations. We estimate that it would take 0.5 hours at $42.40/hr to update the contact information. In aggregate, we estimate an added annual burden of 15 hours (30 entities × 0.5 hr/response) at a cost of $636 (15 hr × $42.40/hr). This would be included in the AM (Data collection and submission) and Applicable GPO (Data Collection and Submission) IC requirements and the ''Open Payments User Guide'' Instrument in the existing PRA package.

i. Summary

TABLE 69: Open Payments Burden Changes

	Total Increase in Burden	Total Decrease in Burden	Total
Teaching Hospital Contact Field	$201,993.60	$158,250.48	$43,743.12
Optional Annual Recertification	$5,088.00	$0.00	$5,088.00
Defining a Physician Owned Distributorship	$0.00	$0.00	$0.00
Disallowing Record Deletion Without Reason	$3,392.00	$0.00	$3,392.00
Disallow Publication Delays of General Payments	$0.00	$0.00	$0.00
Short Term Loans	$0.00	$0.00	$0.00
Remove General Ownership Records	$11,702.00	$0.00	$11,702.00
Updated Contact Information	$636.00	$0.00	$636.00
			$64,561.12

8. The Quality Payment Program (QPP) (42 CFR Part 414 and Section IV. of This Proposed Rule)

The following QPP-specific ICRs reflect this rule's proposed policy changes as well as adjustments to the policies that have been finalized in the CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), the CY 2019, CY 2020 and CY 2021 PFS final rules (83 FR 59452, 84 FR 62568 and 85 FR 84472, respectively).

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

There is a series of ICRs associated with the Quality Payment Program, including for MIPS and Advanced APMs. The MIPS ICRs consist of: Registration for virtual groups (see section V.B.8.b of this proposed rule); QCDR self-nomination applications and other requirements (see section V.B.8.c.(2) of this proposed rule); qualified registry self-nomination applications and other requirements (see section V.B.8.c.(3) of this proposed rule); CAHPS survey vendor applications (see section V.B.8.c.(4) of this proposed rule); Health IT vendors (see section V.B.8.c.(5) of this proposed rule); Open Authorization credentialing and token request process (see section V.B.8.d of this proposed rule); Quality Payment Program Identity Management Application Process (see section V.B.8.e.(3) of this proposed rule); quality performance category data submission by Medicare Part B claims collection type (see section V.B.8.e.(4) of this proposed rule), QCDR and MIPS CQM collection type (see section V.B.8.e.(5) of this proposed rule), eCQM collection type (see section V.B.8.e.(6) of this proposed rule), MVP Quality submission (see section V.B.8.e.(7)(a)(iii) of this proposed rule), and CMS Web Interface collection type (see section V.B.8.e.(8) of this proposed rule); CAHPS for MIPS survey beneficiary participation (see section V.B.8.e.(9) of this proposed rule); group registration for CMS Web Interface (see section V.B.8.e.(10) of this proposed rule); group registration for CAHPS for MIPS survey (see section V.B.8.e.(11) of this proposed rule); MVP registration (see section V.B.8.e.(7)(a)(i) of this proposed rule); subgroups registration (see section V.B.8.e.(7)(a)(ii) of this proposed rule); and call for quality measures (see section V.B.8.f of this proposed rule); reweighting applications for Promoting Interoperability and other performance categories (see section V.B.8.g.(2) of this proposed rule); Promoting Interoperability performance category data submission (see section V.B.8.g.(3) of this proposed rule); call for Promoting Interoperability measures (see section V.B.8.h of this proposed rule); improvement activities performance category data submission (see section V.B.8.i of this proposed rule); nomination of improvement activities (see section V.B.8.j of this proposed rule); nomination of MVPs (see section V.B.8.k of this proposed rule); and opt-out of Physician Compare for voluntary participants (see section V.B.8.o of this proposed rule).

The ICRs for Advanced APMs consist of: Partial Qualifying APM Participant (QP) election (section V.B.8.m of this proposed rule); Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes (sections V.B.8.n.(1) and V.B.8.n.(2) of this proposed rule); and submission of data for QP determinations under the All-Payer Combination Option (section V.B.8.n.(3) of this proposed rule).

(2) Summary of Quality Payment Program Changes: MIPS

The following 10 MIPS ICRs show changes in burden due to the proposed policies in this rule: (1) QCDR self-nomination applications; (2) Qualified Registry self-nomination applications; (3) Quality performance category data submission by Medicare Part B Claims collection type; (4) Quality performance category data submission by QCDR and MIPS CQM collection type; (5) Quality performance category data submission by eCQM collection type; (6) Group registration for CMS Web Interface; (7) CMS Web Interface submission burden; (8) Reweighting applications for Promoting Interoperability and other performance categories; (9) Promoting Interoperability performance category data submission; and (10) Nomination of improvement activities. In aggregate, we estimate the proposed policies will result in a net decrease in burden of 40,010 hours and $4,053,151 for the CY 2022 MIPS performance period/2024 MIPS payment year and 84,803 hours and $8,577,728 for the CY 2023 MIPS performance period/2025 MIPS payment year. The remaining changes to our currently approved burden estimates are adjustments due to the revised assumptions based on the data available at the time of publication of this proposed rule.

We have also added 3 new ICRs (MVP Registration, MVP Quality Submissions, and Subgroups Registration) for the associated burden related to the proposals for implementation of MVPs and subgroups beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. The MVP and subgroup registration ICRs reflect the burden associated with the proposed MVP and subgroup registration requirements described in section IV.A.3.b(4)(f) of this rule. The MVP quality submission ICR reflects the change in burden associated with the proposed requirements for the quality performance category of MVPs described in section IV.A.3.b(4)(d)(ii) of this rule.

We are not making any changes or adjustments to the following ICRs: Registration for virtual groups; CAHPS survey vendor applications; Quality Payment Program Identity Management Application Process; group registration for CAHPS for MIPS survey; CAHPS for MIPS survey beneficiary participation; Open Authorization (OAuth) Credentialing and Token Request Process; nomination of MVPs; call for Promoting Interoperability measures; and improvement activities performance category data submission. See section V.B.8. of this proposed rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our proposed estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted due to two primary reasons. First, we are unable to predict with absolute certainty who will be a QP for the CY 2022 MIPS performance period/2024 MIPS payment year. New eligible clinician participants in Advanced APMs who become QPs would be excluded from MIPS reporting requirements and payment adjustments, and as such, unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians would not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the CY 2022 MIPS performance period/2024 MIPS payment year compared to the CY 2019 MIPS performance period/2021 MIPS payment year, and therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

We acknowledge a recent JAMA article (Khullar, et al., 2021) [248] which includes new data on the burden involved in submitting data for the Quality Payment Program. We have chosen not to include this data in our estimates because of the small sample size included (30 TINs, half of which are APM participants, which we do not include in our estimates). In addition, the article does not indicate the time spent per activity involved in submissions for MIPS, so we are unable to determine if the totals in the article represent only the activities relevant for regulatory burden or separate the totals for the individual ICRs. We seek comment on our assumptions for estimating the burden for clinicians submitting data for the Quality Payment Program.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year. We are not proposing any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process and submission of Data for QP determinations under the All-Payer Combination Option ICRs.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 70 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 70, MIPS eligible clinicians and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. We want to note that we have included subgroups to Table 70 due to the proposed introduction of subgroups for clinicians choosing to report MVPs or the APP in the CY 2023 MIPS performance period/2025 MIPS payment year described in section IV.A.3.b.(2)(d)(ii) of this rule. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 70.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. As discussed in section IV.A.3.c. of this proposed rule, for clinicians in APM Entities, the APM Performance Pathway is available for both ACO and non-ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the CY 2022 MIPS performance period/2024 MIPS payment year, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 PFS final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the improvement activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 PFS final rule (82 FR 53841 through 53844).

[248] JAMA Health Forum.2021;2(5):e210527.doi:10.10001/jamahealthforum.2021.527.

TABLE 70: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures	As virtual group, group, subgroup, individual clinicians, or APM Entity.[a]	As virtual group, group, subgroup, individual clinicians, or APM Entity. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].[b]	As virtual group, group, subgroup, or individual clinicians. MIPS APMs do not submit information. CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. MVP participants electing to submit data for the measures and activities in an MVP must register. MIPS APMs electing the APM Performance Pathway. APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email.[d]

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Submissions by the ACO are not included in burden estimates for this proposed rule because quality data submissions to fulfill requirements of the Shared Savings Program are not subject to the PRA. Section 1899 (42 U.S.C. 1395jjj) states that the Shared Savings Program is not subject to the PRA.

[b] Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[c] The burden estimates for this proposed rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019, CY 2020 and CY 2021 PFS final rules, and continued in this proposed rule create some additional data collection requirements not listed in Table 70. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs Related to MIPS Third-Party Intermediaries (See Section V.B.8.c).

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (New) (OMB 0938–1314) (see section V.B.8.d).

Additional ICRs Related to the Data Submission and the Quality Performance Category (See Section V.B.8.e).

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category (See Section V.B.8.g).

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related To Call for New MIPS Measures and Activities (See Sections V.B.8.f, V.B.8.h, V.B.8.j. and V.B.8.k).

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (OMB 0938–1314).

Additional ICRs Related to MIPS (See Section V.B.8.o).

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs (See Sections V.B.8.m and V.B.8.n).

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule is not proposing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not proposing any changes under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

In section IV.A.3.h. of this rule, we propose multiple changes to the third-party intermediary regulations at § 414.1400. Specifically, we are proposing: (1) Requirement for third-party intermediaries to submit MIPS data for APM Entities; (2) requirement for QCDRs and qualified registries to support MVPs and the APP; (3) requirement for all QCDRs and qualified registries to support subgroup reporting; (4) requirements for approved QCDRs and qualified registries that have not submitted performance data; and (5) new QCDR measure rejection criteria. The proposed burden associated with each of these topics are discussed separately below for qualified registries, QCDRs, and survey vendors.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nomination process annually.[249] The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

The proposed requirements and burden associated with this rule's data submission changes related to QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). As explained below, in this rule we propose to: Adjust the number of self-nomination applications based on current data (from 82 to 90), change the number of QCDR measures submitted for consideration by each QCDR at the time of self-nomination (from 2 to 12), and adjust the average time required to submit information for each QCDR measure (from 2.5 hours to 0.75 hours).

(a) Self-Nomination Process and Other Requirements

In section IV.A.3.h.(1) of this rule, we are proposing reorganization and consolidation of § 414.1400 generally. We assume that this proposal does not change the existing requirements for third-party intermediaries during the self-nomination process. Therefore, we are not revising our burden estimates related to these proposals. We refer readers to § 414.1400 which states that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so. We also refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59998 through 60000), the CY 2020 PFS final rule (84 FR 63116 through 63121) and the CY 2021 PFS final rule (85 FR 84964 through 84969) for our previously finalized requirements and burden for self-nomination of QCDRs and nomination of QCDR measures.

In section IV.A.3.h.(2)(a) of this rule, we propose to: Add APM Entities to § 414.1400(a)(1), and expand the general

[249] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

participation requirements of third-party intermediaries, to third party intermediaries reporting to MIPS on behalf of APM Entities reporting to MIPS in order to align reporting requirements for all participants in MIPS. We are also proposing that beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries must support the APP, and MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. As finalized in the CY 2017 PFS final rule, third-party intermediaries currently support MIPS data submission on behalf of eligible clinicians (81 FR 77016). APM Entities have historically used third party intermediaries for submitting their quality measures to their APMs. Additionally, QCDRs, qualified registries and health IT vendors are required under existing § 414.1400(a)(1) to submit data for the quality, improvement activities, and Promoting Interoperability performance categories in MIPS. Therefore, we anticipate no additional steps being added to the self-nomination process as a result of this proposal for third-party intermediaries to submit MIPS data on behalf of APM Entities, and to support measures and activities in MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. For this proposed rule, we assume that there will be no impact on the time required for QCDRs to complete either the simplified or full self-nomination process because of the above proposals. Additionally, we are proposing to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We anticipate that at the time of self-nomination, QCDRs would be using a checkbox to indicate their compliance for the proposed requirement to support data submission for subgroups beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We assume that this would not impact the overall time estimated for QCDRs to submit their information at the time of self-nomination. Therefore, we are not proposing to make any adjustments in the time required for QCDRs during the simplified or full self-nomination process because of this proposal. However, we anticipate that third-party intermediaries would need to make administrative changes to their existing workflows for submission of MVPs and APP data for clinicians participating as subgroups beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We refer readers to section VII.C.17.f.(2)(f) of this proposed rule where we discuss our impact analysis.

In section IV.A.3.h.(3)(a)(iii) of this rule, to provide further clarity and to better align with the existing policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), we are proposing to codify QCDRs, and qualified registries must conduct validation on the data they intend to submit for the applicable MIPS performance period and provide the results of the executed data validation plan by May 31st of the year following the performance period. Additionally, we are proposing to codify a new requirement at § 414.1400(b)(3)(iv) to state that, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency. We anticipate that this proposal does not make any changes to the existing data validation requirements for QCDRs and qualified registries. Through this proposal, CMS is codifying the finalized policies related to data validation for QCDRs and qualified registries in previous rules. We are not revising our burden estimates as a result of the above proposal and the associated burden was captured in the CY 2017 PFS final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In section IV.A.3.h(3)(a)(i) of this proposed rule, we are proposing new requirements for approved QCDRs and qualified registries that have not submitted performance data. First, we are proposing to create a new requirement at § 414.1400(b)(3)(vii) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 MIPS performance period/2019 MIPS payment year) through the 2020 MIPS performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. If the QCDRs and qualified registries did not submit data, their participation plan must be submitted as part of self-nomination for the 2023 self-nomination period and must be accepted by CMS to continue to be an approved QCDR or qualified registry. We are also proposing to codify a new requirement at paragraph (b)(3)(viii) to state that, beginning with the CY 2024 MIPS performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS's approval. Under this proposal, the participation plan must explain the QCDR and/or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third-party intermediary on behalf of clinicians or groups. The vendor must also explain why they should still be allowed to participate as a qualified vendor.

Based on our review of the existing list of approved QCDRs that did not submit performance data since the inception of MIPS (CY 2017 MIPS performance period/2019 MIPS payment year), we estimate that approximately 10 QCDRs will submit participation plans for the CY 2022 and the CY 2023 self-nomination periods. Similar to our assumptions for submission of a Corrective Action Plan (CAP) in the CY 2021 PFS final rule (85 FR 84968), we anticipate that the effort involved in developing a participation plan including the proposed policies specified in this rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $95.22/hr. For the CY 2022 MIPS performance period/2024 MIPS payment year, we estimate an annual burden of 30 hours (3 hr × 10 participation plans) at a cost of $2,857 (30 hr × $95.22/hr) for QCDRs that would need to develop and submit a participation plan.

In section IV.A.3.h.(4) of this rule, we are proposing to codify new requirements that if a QCDR measure owner is not an approved active QCDR for a given self-nomination period, that QCDR measure will not be available for use. Additionally, we propose to codify a new requirement in section IV.A.3.h.(1)(d)(iv) and add a rejection criterion at § 414.1400(b)(4)(iv)(M) to state, a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. It was finalized in the CY 2018 PFS final rule (82 FR 53813) that beginning with the CY 2018 MIPS performance period/2020 MIPS payment year, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. Additionally, in the CY 2020 PFS final rule (84 FR 63070 through 63073), we finalized the QCDR measure rejection criteria

considerations. Specifically, we stated that all previously approved QCDR measures and new QCDR measures would be reviewed on an annual basis (as a part of the QCDR measure review process that occurs after the self-nomination period closes on September 1st) to determine whether they are appropriate for the program. In the CY 2020 PFS final rule, we indicated to stakeholders that as information becomes available in future years, we will revisit our assumptions to better reflect the impact of these requirements on QCDRs and the quantity of measures annually (84 FR 63118 through 63119). As discussed in the CY 2019 PFS final rule (83 FR 60000) and CY 2020 PFS final rule (84 FR 63118), we are not accounting for QCDR measure licensing costs as part of our burden estimate.

Based on the number of QCDR measures submitted at the time of self-nomination for the CY 2021 MIPS performance period/2023 MIPS payment year, we assume that 82 QCDRs will submit 984 measures for consideration in the CY 2022 MIPS performance period/2024 MIPS payment year, approximately 12 measures per QCDR, on average. We anticipate that out of the 984 measures, 820 measures would be existing or borrowed measures, approximately 10 measures submitted per QCDR self-nomination application. The remaining 104 measures would be new measures, approximately 2 measures on average per QCDR.

Using the above assumption that each QCDR submitting measures for approval during the self-nomination process will submit approximately 12 measures (10 existing or borrowed measures + 2 new measures), we estimate an increase of 10 measures from the currently approved estimate of 2 measures per QCDR. The estimated increase in the total number of measures submitted by a QCDR at the time of self-nomination is due to the inclusion of the existing or borrowed QCDR measures in our assumptions. Additionally, we anticipate that less information is needed for a QCDR to submit an existing or borrowed measure for approval, therefore, we estimate that the time needed for a QCDR to submit an existing or borrowed measure is 0.5 hours, independent of the selection of the simplified or full self-nomination process. Consistent with our assumption in the CY 2020 PFS final rule (84 FR 63119), we continue to estimate that each QCDR will require 2 hours to submit a new QCDR measures for approval, independent of the selection of the simplified or full self-nomination process. To account for the difference in the time for submission of new vs existing QCDR measures for approval, we are using the weighted average to estimate the time required for QCDR measure submission at the time of self-nomination. Therefore, we assume that the weighted average of the time required for each QCDR to submit a new or existing or borrowed measure for approval during the self-nomination process is 0.75 hours [((2 new measures × 2 hours) + (10 existing or borrowed measures × 0.5 hours))/total # of measures (12)]. Based on the above assumptions, we are proposing to revise our estimates in the amount of time required for a QCDR to submit measures during the self-nomination process from a total of 2 hours to approximately 0.75 hours, a decrease of 1.75 hours from the currently approved estimated burden per QCDR measure submission.

In the CY 2019 PFS final rule, we estimated that it would take 0.5 hours and 3 hours for a QCDR to submit all the required information during the simplified and full self-nomination process, respectively (83 FR 59999). Based on our experience with the amount of time needed for QCDRs during the 2020 self-nomination period, we assume that the estimated time of 3 hours per QCDR for a full self-nomination process is an overestimate and are proposing to revise our estimated time required for the QCDR full-self-nomination process to 2.5 hours, a decrease of 0.5 hours. We are not making any adjustments in the amount of time needed for simplified self-nomination process.

Based on the trends noticed in the number of QCDRs that submit applications for self-nominations and consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84965), we estimate that 90 QCDRs will submit applications for consideration during the self-nomination process for the CY 2022 MIPS performance period/2024 MIPS payment year, an increase of 8 applications from the currently approved estimate of 82. For QCDRs that submit measures as part of their self-nomination process, while simultaneously accounting for the estimated increase in the number of existing or borrowed QCDR measures submitted with the self-nomination application and the decrease in the estimated time for the QCDR full-nomination process, we are proposing to revise our estimated time for the QCDR self-nomination process to a minimum of 9.5 hours [0.5 hours for the simplified self-nomination process + (12 measures × 0.75 hr/measure for QCDR measure submission)] and a maximum of 11.5 hours [2.5 hours for the full self-nomination process + (12 measures × 0.75 hr/measure for QCDR measure submission)], an increase of 4 hours at a cost of $380.88 (4 hr × $95.22/hr) and 3.5 hours at a cost of $333.27 (3.5 hr × $95.22/hr) from the currently approved burden per respondent estimate in the CY 2021 PFS final rule (85 FR 84965).

Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84967), based on the number of targeted audits received for the 2020 self-nomination period, we estimate that 20 QCDRs will submit targeted audits for the CY 2022 MIPS performance period/2024 MIPS payment year, an increase of 3 from the currently approved estimate of 17 QCDRs submitting targeted audits in the CY 2021 PFS final rule. Using the currently approved unchanged burden per respondent estimate, the proposed estimated burden associated with QCDRs completing targeted audits will range from 100 hours (20 audits × 5 hr/audit) at a cost of $9,522 (20 audits × $476.10/audit) for the simplified self-nomination process to 200 hours (20 audits × 10 hr/audit) at a cost of $19,044 (20 audits × $952.20/audit) for the full self-nomination process (see Table 68 for the cost per audit). We assume that this would adjust our burden estimates for targeted audits by +15 hours (+3 respondents × 5 hr/audit) at a cost of $1,428.30 (15 hrs × $95.22/hr) and +30 hours (+3 respondents × 10 hr/audit) at a cost of $2,856.60 (30 hrs × $95.22/hr) for the simplified and full self-nomination process, respectively. Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on behalf of MIPS eligible clinicians.

As shown in Table 71, we assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $95.22/hr.

Using the change in the number of respondents and the estimated time per respondent for QCDRs that submit measures for approval during the self-nomination process, the proposed annual burden for the simplified and full-self nomination process will range from 855 hours (90 QCDRs × 9.5 hr) to 1,035 hours (90 QCDRs × 11.5 hr) at a cost ranging from $81,413 (855 hr × $95.22/hr) and $98,553 (1,035 hr × $95.22/hr), respectively.

As shown in Table 71, combined with our proposed adjusted estimate of annual burden for targeted audits and the proposed burden for submission of participation plans, we are proposing to

revise our estimated burden for the QCDR self-nomination process, ranging from 985 hours [855 hr (90 QCDRs × 9.5 hr) + 100 hr (20 audits × 5 hr) + 30 hr (10 participation plans × 3 hr)] at a cost of $93,792 [$81,414 (855 hr × $95.22/hr) + $9,522 (20 audits × $476.10/audit) + $2,857 (30 hr × $95.22/hr)] for a simplified self-nomination process to 1,265 hours [1,035 hr (90 QCDRs × 11.5 hr) + 200 hr (20 audits × 10 hr) + 30 hr (10 participation plans × 3 hr)] at a cost of $120,454 [$98,553 (1,035 hr × $95.22/hr) + $19,044 (20 audits × $952.20/audit) + $2,857 (30 hr × $95.22/hr)] for the full self-nomination process.

TABLE 71: Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	90	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	90
Total Applications	**90**	**90**
Annual Hours Per QCDR for Simplified Process (c)	9.5	9.5
Annual Hours Per QCDR for Full Process (d)	11.5	11.5
Annual Hours for Self-nomination (e) = (a) * (c) and (b) * (d)	**855**	**1,035**
# of Hours per Completion of Targeted Audit (e)	**5**	**10**
Annual Hours for Completion of 20 Targeted Audits (f)	**100**	**200**
# of Hours per Submission of Participation Plan (g)	**3**	**3**
Annual Hours for Submission of 10 Participation Plans (h)	**30**	**30**
Total Annual Time (Hours) (i)	**985**	**1,265**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $95.22/hr) (j) = (c) * $95.22/hr	$904.60	$904.60
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $95.22/hr) (k) = (d) * $95.22/hr	$1,095.03	$1,095.03
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $95.22/hr) (l) = (e) * $95.22/hr	$476.10	$952.20
Cost Per Participation Plan (@ computer systems analyst's labor rate of $95.22/hr) (m) = (g) * $95.22/hr	$285.70	$285.70
Total Annual Cost (l) = (a) * (h) + (b) * (i) + (j) * 20 + (k) * 10	**$93,792**	**$120,454**

As shown in Table 72, for the CY 2022 MIPS performance period/2024 MIPS payment year, independent of the proposed change to our per response time estimate, the estimated increase in 8 respondents from the currently approved 82 respondents to 90 results in an increase of between +76 hours (+8 respondents × 9.5 hrs/respondent for the simplified self-nomination process) and +92 hours (+8 respondents × 11.5 hrs/respondent for the full self-nomination process) at a cost of between +$7,237 (+8 respondents × $904.60/respondent for the simplified self-nomination process) and +$8,760 (+8 respondents × $1,095.03/respondent for the full self-nomination process) (see Table 71 for the cost per QCDR).

Accounting for the proposed change in time required for the QCDR self-nomination process results in an adjustment of between +328 hours (82 respondents × +4 hr for the simplified self-nomination process or also referred to as minimum burden) at a cost + $31,232 [82 respondents × $380.88 (+4 hr × $95.22/hr)/respondent) and +287 hours (82 respondents × 3.5 hr for the full self-nomination process or also referred to as maximum burden) at a cost of and +$27,328 (82 respondents × $333.27 (+3.5 hr × $95.22/hr)/respondent). The reason for the increase in minimum burden compared to the maximum burden is due to an increase in the change in the number of hours required for the simplified self-nomination process compared to the increase in the number of hours for the full self-nomination process.

In aggregate, as shown in Table 72, when these impacts are combined with the proposed estimate for targeted audits and participation plans discussed above, the net impact ranges between +449 hours [76 hr (+8 respondents × 9.5 hrs/respondent) + 15 hr (+3 targeted audits × 5 hrs/audit) + 30 hr (10 participation plans × 3 hr/plan) + 328 hr (82 respondents × 4 hr)] at a cost of $42,754 ($7,237 + $1,428 + $2,857 + $31,232) for the simplified self-nomination process (also referred to as minimum burden) and +439 hours [92 hr (+8 respondents × 11.5 hrs/respondent) + 30 hr (+3 targeted audits × 10 hrs/audit) + 30 hr (10 participation plans × 3 hr/plan) + 287 hr (+82 respondents × 3.5 hr)] at a cost of $41,802 [$8,760 (+8 respondents × $1,095.03/respondent + $2,857 (30 hr × $95.22/hr) + $2,857 (30 hr × $95.22/hr) + $27,328 (82 respondents × $333.27/respondent)] for the full self-nomination process (also referred to as maximum burden) for the CY 2022 MIPS performance period/2024 MIPS payment year.

TABLE 72: Change in Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum	Maximum
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	536	826
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (See Table 71)	985	1,265
Difference (c) = (b) - (a)	**+449 hr**	**+439 hr**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$51,038	$78,652
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (See Table 71)	$93,792	$120,454
Difference (f) = (e) - (d)	**+$42,754**	**+$41,802**

(b) QCDR Measure Requirements

In the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), we discussed that beginning with the 2018 performance period and for future program years, QCDR vendors may seek permission from another QCDR to use an existing measure that is owned by the other QCDR. Additionally, in the CY 2020 Quality Payment Program rule (84 FR 63070 through 63073) we finalized the QCDR measure rejection criteria considerations.

In section IV.A.3.h.(4)(a)(i)(A)(aa) of this rule, we are proposing to codify a new requirement and add a rejection criterion that a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. Additionally, we are proposing to codify new requirements that if a QCDR measure owner is not an approved active QCDR for a given self-nomination period, that QCDR measure will not be available for use. The inactive QCDR measure owner has the option to transfer ownership of the QCDR measure to an active QCDR or agree upon terms set forth with the active QCDR allowing co-ownership of the QCDR measure. We refer readers to section IV.A.3.h.(4)(a)(i)(A) of this rule for additional details on the proposed policies for transfer of ownership of QCDR measures. This proposal is to codify the existing requirements for the QCDR self-nomination process. We are not proposing to revise our burden estimates as result of this proposal because we assume that this does not change the requirements, or the time required for a QCDR to submit information for a QCDR measure at the time of self-nomination.

Additionally, we are proposing to codify another rejection criterion at § 414.1400(b)(4)(iv)(N) to state that, if a QCDR measure owner is not approved during a given self-nomination period, any associated QCDR measures with that QCDR would also not be approved. We are not revising our burden estimates as a result of the above proposal because we assume that there would not be additional requirements for QCDRs to submit at the time of self-nomination. This is part of the measure specification requirements for QCDRs which submit measures for approval during the self-nomination process.

(3) Qualified Registry Self-Nomination Process and Other Requirements

The requirements and burden associated with this rule's data submission changes related to qualified registries will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to § 414.1400 which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so. We also refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59997 through 59998), CY 2020 PFS final rule (84 FR 63114 through 63116) and the CY 2021 PFS final rule (85 FR 84967 through 85 FR 84969) for our previously finalized requirements and burden for self-nomination of qualified registries.

In section IV.A.3.h.(1) of this rule, we are proposing reorganization and consolidation of § 414.1400 generally. We assume that this proposal does not change the existing requirements for third-party intermediaries during the self-nomination process. Therefore, we are not revising our burden estimates related to these proposals.

In section IV.A.3.h.(2)(a) of this rule, we are proposing to add APM Entities to § 414.1400(a)(1), expanding the general participation requirements of third-party intermediaries, to third party intermediaries reporting to MIPS on behalf of APM Entities reporting to MIPS to align reporting requirements for all participants in MIPS. We are also proposing that beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries must support APP, and MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. As finalized in the CY 2017 PFS final rule, third-party intermediaries currently support MIPS data submission on behalf of eligible clinicians (81 FR 77016). APM Entities have historically used third party intermediaries for submitting their quality measures to their APMs. Additionally, QCDRs, qualified registries and health IT vendors are required under existing § 414.1400(a)(1) to submit data for the quality, improvement activities, and promoting interoperability performance categories in MIPS. Like our discussion for QCDRs above, we anticipate no additional steps being added to the qualified registry self-nomination process as a result of this proposal for third party intermediaries to submit MIPS data on behalf of APM Entities, and to support measures and activities in MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. For this proposed rule, we assume that there will be no impact on the time required for qualified registries to complete either the simplified or full self-nomination process because of the above proposals. Additionally, we are proposing to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We anticipate that at the time of self-nomination, qualified registries would be using a checkbox to indicate their compliance for the proposed requirement to support data submission

for subgroups beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We assume that this would not impact the overall time estimated for qualified registries to submit their information at the time of self-nomination. Therefore, we are not proposing to make any adjustments in the time required for qualified registries during the simplified or full self-nomination process because of this proposal. However, we anticipate that third-party intermediaries would need to make administrative changes to their existing workflows for submission of MVPs and APP data for clinicians participating as subgroups beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We refer readers to section VII.C.17.f.(2)(f) of this rule where we discuss our impact analysis.

Based on previous trends for the number of self-nominations for qualified registries received during the 2020 self-nomination period for the CY 2021 MIPS performance period/2023 MIPS payment year and consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84967), we anticipate an increase in the number of submissions from qualified registries for the CY 2022 MIPS performance period/2024 MIPS payment year. Therefore, we estimate that we will receive 210 nomination applications from qualified registries for the CY 2022 MIPS performance period/2024 MIPS payment year, an increase of 27 from the currently approved estimate of 183. Based on our estimates in the CY 2021 PFS final rule (85 FR 84967), we are proposing to adjust the estimated number of qualified registries that will submit targeted audits for the CY 2022 MIPS performance period/2024 MIPS payment year. Similar to our assumptions in the CY 2021 PFS final rule (85 FR 84967) and based on the number of targeted audits received from qualified registries for the CY 2019 MIPS performance period/2021 payment year, we estimate 63 qualified registries would be required to conduct targeted audits, an increase of 7 from the currently approved estimate of 56. Therefore, we estimate the total impact associated with qualified registries completing targeted audits will range from 315 hours (63 registries ×5 hours/audit) at a cost of $29,994 (63 registries × $476.10/audit) to 630 hours (63 registries × 10 hours/audit) at a cost of $59,989 (63 registries × $952.20/audit) for the simplified and full self-nomination process, respectively (see Table 71 for the cost per audit). We assume that this would adjust our burden estimates for targeted audits by +35 hours (+7 respondents × 5 hr/audit) at a cost of $3,332.70 (35 hrs × $95.22/hr) and +70 hours (+7 respondents × 10 hr/audit) at a cost of $6,665.40 (70 hrs × $95.22/hr) for the simplified and full self-nomination process, respectively.

Using our currently approved time per response estimate of 3 hours, the resulting adjustment in burden for QCDRs and qualified registries to submit CAPs is 30 hours (10 respondents × 3 hrs/respondent) at a cost of $2,857 (30 hours × $95.22/hr).

In section IV.A.3.h.(3)(a)(1) of this proposed rule, we are proposing new requirements for approved QCDRs and qualified registries that have not submitted performance data. First, we are proposing to create a new requirement at paragraph § 414.1400(b)(3)(vii) to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 MIPS performance period/2019 MIPS payment year) through the CY 2020 MIPS performance period/2022 MIPS payment year, to submit a participation plan as part of their self-nomination for CY 2023. Exceptions to this requirement may occur if data is received for the CY 2021 MIPS performance period/2023 MIPS payment year. Under this scenario, QCDRs and qualified registries would not need to submit a participation plan for the 2023 self-nomination process. If the QCDRs and qualified registries did not submit data, their participation plan must be submitted as part of self-nomination for 2023 MIPS self-nomination period and must be accepted by CMS to continue to be an approved QCDR or qualified registry. We are also proposing to codify a new requirement that, beginning with the CY 2024 MIPS performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. Under this proposal, the participation plan must explain the QCDR and/or qualified registry's detailed plans about how the vendor intends to encourage clinicians to submit MIPS data to CMS through the third-party intermediary on behalf of clinicians or groups. The vendor must also explain why they should still be allowed to participate as a qualified vendor.

Based on our review of the existing list of approved qualified registries that did not submit performance data since the inception of MIPS (CY 2017 MIPS performance period/2019 MIPS payment year), we estimate that 19 qualified registries will submit participation plans for the CY 2023 MIPS self-nomination period. Similar to our assumptions used for submission of a CAP in the CY 2021 PFS final rule (85 FR 84968), we anticipate that the effort involved in developing a participation plan including the proposed policies specified in this rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $95.22/hr. For the CY 2023 MIPS performance period/2025 MIPS payment year, we estimate an annual burden of 57 hours (3 hr × 19 participation plans) at a cost of $5,428 (57 hr × $95.22/hr) for qualified registries to develop and submit a participation plan.

As stated above, based on the number of self-nominations received for the CY 2021 MIPS performance period/2023 MIPS payment year, we are proposing to adjust the estimated number of qualified registries that would self-nominate for the CY 2023 performance period to 210, an increase of 27 from the currently approved estimate of 183 in the CY 2021 PFS final rule (85 FR 84969). In the CY 2019 PFS final rule, we estimated that it would take 3 hours for a qualified registry to submit all the required information during the full self-nomination process (83 FR 59998). Based on our experience with the self-nomination process, we believe that the number of fields needed to be submitted for a qualified registry are fewer than those needed for a QCDR. We assume that our previous assumption of 3 hours is an overestimate. Therefore, we propose to revise our estimated time required for a qualified registry submitting a full-self-nomination process to 2 hours, a decrease of 1 hour.

We assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $95.22/hr. Using the change in estimated burden per respondent time, associated with the self-nomination process range from a minimum of 0.5 hours to a maximum of 2 hours, we estimate that the annual burden will range from 105 hours (210 qualified registries × 0.5 hr) to 420 hours (210 qualified registries × 2 hr) at a cost ranging from $9,998 (105 hr × $95.22/hr) and $39,992 (420 hr × $95.22/hr), respectively (see Table 73).

Combined with our estimates of burden associated with completing targeted audits and developing and submitting participation plans and corrective action plans, our total burden estimate ranges from 507 hours [105 hr (210 qualified registries × 0.5 hr) + 57 hr (+19 participation plans × 3hr/plan)

+ 315 hr (63 targeted audits × 5 hours/audit) + 30 hr (10 CAPs × 3 hr) at a cost of $48,277 [$9,998 (105 hr × $95.22/hr) + $5,428 (57 hr × $95.22/hr) + $29,994 (63 registries × $476.10/audit) + $2,857 (30 hours × $95.22/hr)] to 1,137 hours [420 hr (210 qualified registries × 2 hr) + 57 hr (+19 participation plans × 3hr/plan) + 630 hr (63 targeted audits × 10 hours/audit) + 30 hr (10 CAPs × 3 hr)] at a cost of $108,266 [$39,992 (420 hr × $95.22/hr) + $5,428 (57 hr × $95.22/hr) + $59,989 (63 registries × $952.20/audit) + $2,857 (30 hours × $95.22/hr) for the simple self-nomination process (see minimum burden in Table 73 below) and full self-nomination process (see maximum burden in Table 73) respectively.

Based on the assumptions discussed in this section, we provide a proposed estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 73: Estimated Burden for Qualified Registry Self-Nomination

	Minimum	Maximum
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	210	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	210
Total Applications (c)	**210**	**210**
Total Annual Hours Per Qualified Registry for Simplified Process (d)	0.5	0
Total Annual Hours Per Qualified Registry for Full Process (e)	0	2
Total Annual Hours for Self-Nomination for min. (f) = (a) * (d) and max. (b) * (e)	**105**	**420**
Total Annual Hours for Completion of 63 Targeted Audits (g)	**315**	**630**
Total Annual Hours for development and submittal of 19 Participation Plans (h)	**57**	**57**
Total Annual Hours for Submittal of 10 CAPs (i)	**30**	**30**
Total Annual Time (Hours) (j) = (e) + (f) + (g) + (h)	**507**	**1,137**
Cost Per Simplified Process Per Qualified Registry (@ computer systems analyst's labor rate of $95.22/hr) (k)	$47.61	$47.61
Cost Per Full Process Per Qualified Registry (@ computer systems analyst's labor rate of $95.22/hr) (l)	$190.44	$190.44
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $95.22/hr) (m)	$476.10	$952.20
Cost Per Participation Plan (@ computer systems analyst's labor rate of $95.22/hr) (n)	$285.66	$285.66
Cost per CAP (@ computer systems analyst's labor rate of $95.22/hr) (o)	$285.66	$285.66
Total Annual Cost for min. (p) = (a) * (k) + (m) * 63 + (n) * 19 + (o) * 10 and max. (b) * (l) + (m) * 63 + (n) * 19 + (o) * 10	**$48,277**	**$108,266**

As shown in Table 74, for the CY 2022 MIPS performance period/2024 MIPS payment year, independent of the proposed change to our per response time estimate, the estimated increase in 27 respondents from the currently approved 183 respondents to 210 results in an increase of between +13.5 hours (+27 respondents × 0.5 hrs/respondent) at a cost of +$1,285 (13.5 hours × $95.22/hr) and +54 hours (+27 respondents × 2 hrs/respondent) at a cost of +$5,142 (54 hours × $95.22/hr). Accounting for the proposed change in time required for the qualified registry self-nomination process results in an adjustment of 0 hours for the simplified self-nomination process and −183 hours (183 respondents × −1 hours) at a cost of −$17,425 (−183 hours × $95.22/hr) for the full self-nomination process.

When the above impacts are combined with the proposed estimates for targeted audits, participation plans and corrective action plans discussed above, the net impact ranges between +106 hours [13.5 hr (+27 respondents × 0.5 hrs/respondent) + 0 hr + 35 hr (+7 audits × 5 hr/audit) + 57 hr (+19 participation plans × 3hr/plan) + 0 hr)] at $10,046 [($1,286 (13.5 hours × $95.22/hr) + $0 + $3,333 (35 hrs × $95.22/hr) + $5,428 (+57 hr × $95.22/hr) + $0)] for the simplified self-nomination process and −2 hours [(54 hr (+27 respondents × 2 hrs/respondent) −183 hr (183 respondents × −1 hours) + 70 hr (+7 audits × 10hr/audit) + 57 hr (+19 participation plans × 3hr) + 0 hr)] at a cost of −$190 [($5,142 (54 hours × $95.22/hr) − $17,425 (−183 hours × $95.22/hr) + $6,665 (70 hrs × $95.22/hr) + $5,428 (+57 hr × $95.22/hr) + $0)] for the full self-nomination process for the CY 2022 MIPS performance period/2024 MIPS payment year.

TABLE 74: Change in Estimated Burden for Qualified Registry Self Nomination

	Minimum	Maximum
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	401	1,139
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (See Table 73)	507	1,137
Difference (c) = (b) - (a)	**+106**	**-2**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$38,231	$108,456
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (See Table 73)	$48,277	$108,266
Difference (f) = (e) - (d)	**+$10,046**	**--$190**

(4) Survey Vendor Requirements

In section IV.A.3.h(2)(b)(ii) of this rule, we are proposing to require CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. Because of this proposal, we anticipate no additional steps being added to the requirements for CAHPS for MIPS survey vendors to submit a participation form and assume there will be no impact on the time required for the survey vendors. Therefore, we are not proposing to make any adjustments in the time required for CAHPS survey vendors to submit the because of this proposal. The requirements and burden for CAHPS survey vendors to submit data for eligible clinicians are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any changes under that control number.

(5) Health IT Vendors

In section IV.A.3.h.(2)(b) of this rule, we propose to create a new requirement at paragraph § 414.1400(c)(1)(iii) to state that, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. Health IT vendors may also support the APP. Additionally, we propose to require health IT vendors to support subgroup reporting beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We do not anticipate any requirement/burden changes as it relates to the support of reporting data.

d. ICR Regarding Open Authorization (OAuth) Credentialing and Token Request Process

This rule is not proposing any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

e. ICRs Regarding Quality Data Submission (§§ 414.1318, 414.1325, 414.1335, and 414.1365)

(1) Background

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77502 through 77503), CY 2018 Quality Payment Program final rule (82 FR 53908 through 53912), CY 2019 PFS final rule (83 FR 60000 through 60003), CY 2020 PFS final rule (84 FR 63121 through 63124), and the CY 2021 PFS final rule (85 FR 84970 through 84974) for our previously finalized requirements for data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as MIPS eligible clinicians and those who submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the CY 2022 MIPS performance period/2024 MIPS payment year. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future CY 2022 MIPS performance period/2024 MIPS payment year (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the CY 2019 MIPS performance period/2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). As in the CY 2021 PFS final rule, we continue to use CY 2019 MIPS performance period/2021 MIPS payment year data to estimate the number of respondents in the CY 2022 PFS proposed rule.

There may be an undercount in submissions due to the PHE for COVID–19, because of the automatic extreme and uncontrollable circumstances policy, and application-based policy that allowed clinicians to elect not to submit during the submission period for the CY 2019 MIPS performance period/2021 MIPS payment year that we are using to inform our burden estimates. Despite this limitation, we believe the data from the CY 2019 MIPS performance period/2021 MIPS payment year is still the best data source available as it most accurately reflects the impacts of policies finalized in previous rules and trends toward increased group reporting.

In section IV.A.3.d.(1)(d) of this rule, we are proposing to continue the CMS Web Interface measures as a collection type for the CY 2022 MIPS performance period/2024 MIPS payment year. Additionally, we are proposing to sunset the CMS Web Interface measures as a collection type/submission type starting with the CY 2023 MIPS performance period/2025 MIPS payment year. In the CY 2021 PFS final rule (85 FR 84981), we finalized the sunset of CMS Web Interface as a collection type for the CY 2022 MIPS

performance period/2024 MIPS payment year. We refer readers to the CY 2021 PFS final rule for discussion on our assumptions for the CY 2022 MIPS performance period/2024 MIPS payment year, where we estimated a burden of zero due to our assumption that all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types. Based on the number of groups that submitted quality performance data via the CMS Web Interface in the CY 2019 MIPS performance period/2021 MIPS payment year, we are not able to ascertain what alternative collection type(s) the groups would elect. In order to estimate the number of groups that will select each of these collection types, we first clustered the number of groups which submitted data via the CMS Web Interface collection type during the CY 2019 MIPS performance period/2021 MIPS payment year by practice size (between 25 and 49 clinicians, between 50 and 99 clinicians, etc.). Then, for each cluster, we allocated these groups to each of the MIPS CQM and QCDR and eCQM collection types based on the percent of TINs that submitted MIPS data via these two collection types. For example, of the 1,629 TINs with a practice size of 25 to 49 clinicians which submitted data for the CY 2019 MIPS performance period/2021 MIPS payment year, 1,066 (65 percent) submitted data via the MIPS CQM and QCDR collection type and 563 (35 percent) submitted data via the eCQM collection type. We applied these percentages to the 7 TINs with a practice size of 25 to 49 clinicians which submitted data via the CMS Web Interface collection type for the CY 2019 MIPS performance period/2021 MIPS payment year to estimate that 4 (7 TINs $\times$ 0.56) would elect to submit data via the MIPS CQM and QCDR collection type and the remaining 3 (7 TINs $\times$ 0.44) would elect to submit data via the eCQM collection type. In total, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, we estimate that 64 of the 114 groups that submitted data via the CMS Web Interface collection type for the CY 2019 MIPS performance period/2021 MIPS payment year will submit quality data via the MIPS CQM and QCDR collection type and 50 groups will now submit quality data via the eCQM collection type. Note that the 114 groups is an increase of 114 from our currently approved estimate of 0 groups in the CY 2022 performance period/2024 payment year. We also performed this analysis to determine the number of clinicians that would be affected and would need to submit quality data via an alternate collection type beginning with the CY 2023 performance period/2025 payment year. In total, of the estimated 45,599 individual clinicians affected by this provision, we estimate that 11,432 would submit quality data as part of a group via the MIPS CQM and QCDR collection type and 34,167 would submit quality data as part of a group via the eCQM collection type. These estimates are reflected in Tables 78 and 80 and the associated changes in burden are reflected in Tables 79 and 81. In aggregate, as discussed in section V.B.8.p of this proposed rule, we estimate the provision to sunset the CMS Web Interface measures as a collection type/submission type will result in a net decrease in quality performance data reporting burden while acknowledging the additional financial impacts on clinicians as discussed in section VII.F.17.f.(2)(a) of the Regulatory Impact Analysis. We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2020 and CY 2021 PFS final rules (84 FR 63122 and 85 FR 84972), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. As stated in section V.B.8.e.(2) of this proposed rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the CY 2022 MIPS performance period/2024 MIPS payment year, we used the Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period. We elected to use this data source because the overlap with the data submissions for the CY 2019 MIPS performance period/2021 MIPS payment year enabled the exclusion of Partial QPs that elected to not participate in MIPS and required fewer assumptions as to who is a QP or not. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their reporting as a group or individual for the CY 2019 MIPS performance period/2021 MIPS payment year.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded from this collection of information section but is discussed in the regulatory impact analysis section of this proposed rule because sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[250] Tables 72, 73, and 74 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 75 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the CY 2022 and 2023 MIPS performance periods/2024 and 2025 MIPS payment years based on data from the CY 2019 MIPS performance period/2021 MIPS payment year.

For the CY 2022 MIPS performance period/2024 MIPS payment year, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and Web Interface. For the CY 2023 MIPS performance period/2025 MIPS payment year, respondents would no longer have the option to submit quality performance category data via the Web Interface. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

For the CY 2023 MIPS performance period/2025 MIPS payment year, we propose in section IV.A.3.b.(2)(d) of this rule that clinicians in MIPS would have the option to submit measures and activities in MVPs. We refer readers to section IV.A.3.b.(4) of this rule for additional details on the proposed reporting requirements for MVPs. For the quality performance category of MVPs, we assume that MVP Participants would choose to report via the Medicare

[250] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

Part B claims, QCDR, MIPS CQMs, and eCQMs collection type. Table 87 of this rule includes the estimated burden for collecting data for the quality performance category of MVPs.

As shown in Table 75, using participation data from the CY 2019 MIPS performance period/2021 MIPS payment year, combined with the estimate of QPs for the CY 2022 MIPS performance period/2024 MIPS payment year, we estimate a total of 625,703 clinicians will submit quality data as individuals or groups in each of the CY 2022 and 2023 MIPS performance periods/2024 and 2026 MIPS payment years, a decrease of 25,811 clinicians when compared to our estimate of 651,514 clinicians in the CY 2021 PFS final rule (85 FR 84972). For the CY 2022 performance period/2024 payment year, we estimate 28,252 clinicians will submit data as individuals for the Medicare Part B claims collection type; 279,247 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 273,819 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 44,385 clinicians will submit as part of groups via the CMS Web Interface. Compared to the CY 2022 MIPS performance period/2024 MIPS payment year burden estimated in the CY 2021 PFS final rule (85 FR 84972), these are decreases from the estimates of 29,273, 295,941, and 326,300 for Medicare Part B claims, MIPS CQM and QCDR, eCQM, and an increase of 44,385 for the CMS Web Interface collection types, respectively. These adjustments are due to the availability of updated data from the CY 2019 MIPS performance period/2021 MIPS payment year and the delay in sunsetting the CMS Web Interface from the CY 2022 MIPS performance period/2024 MIPS payment year to the CY 2023 MIPS performance period/2025 MIPS payment year. For the CY 2023 performance period/2025 payment year, we estimate 25,427 clinicians will submit data as individuals for the Medicare Part B claims collection type; 288,637 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 311,326 clinicians will submit data as individuals or as part of groups via the eCQM collection type.

Table 75 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 75: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type (as Individual Clinicians or as Part of Groups)

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2022 MIPS performance period (excludes QPs) (a)	28,252	279,247	273,819	44,385	625,703
* Currently approved 2022 MIPS performance period (excludes QPs) (b)	29,273	295,941	326,300	0	651,514
Difference (c) = (a) - (b)	-1,021	-16,694	-52,481	44,385	-25,811
2023 MIPS performance period prior to MVP and Web Interface adjustments (excludes QPs) (d)	28,252	295,941	326,300	0	650,493
Adjustment for Web Interface Sunset (e)	0	24,767	19,618	0	44,385
Adjustment for Shift to MVP (10% reduction) (f) = ((d) + (e)) * -.1	-2,825	-32,071	-34,592	0	-69,488
2023 after adjustments (g) = (d) + (e) + (f)	25,427	288,637	311,326	0	625,390
* Currently approved 2022 MIPS performance period (excludes QPs) (h)	29,273	295,941	326,300	0	651,514
Difference (i) = (g) - (h)	-3,846	-7,304	-14,974	-0	-26,124

*Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the 2019 MIPS performance period/2021 MIPS payment year. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 76 uses methods similar to those described to estimate the number of clinicians that will submit data as individual clinicians via each collection type in the CY 2022 and CY 2023 MIPS performance periods/2024 and 2025 MIPS payment years. For the CY 2022 MIPS performance period/2024 MIPS payment year, we estimate that approximately 28,252 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 40,507 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 40,446 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2019 MIPS performance period/2021 MIPS payment year, these are decreases of −1,021, −833, and −1,809 respondents from the currently approved estimates of 29,273, 41,340, and 42,255 for the Medicare Part B claims, MIPS CQM and

QCDR, and eCQM collection types, respectively.

As shown in Table 76, for the CY 2023 MIPS performance period/2025 MIPS payment year, we estimate that approximately 25,427 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 36,456 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 36,401 clinicians will submit data as individuals using eCQMs collection type. Based on performance data from the CY 2019 MIPS performance period/2021 MIPS payment year, these are decreases of −3,846, −4,884, and −5,854 respondents from the currently approved estimates of 29,273, 41,340, and 42,255 for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, respectively.

TABLE 76: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2022 MIPS Performance Period (excludes QPs) (a)	28,252	40,507	40,446	0	109,205
*Currently approved 2022 MIPS performance period (excludes QPs) (b)	29,273	41,340	42,255	0	112,868
Difference (c) = (a) - (b)	-1,021	-833	-1,809	0	-3,663
2023 MIPS Performance Period (excludes QPs) prior to MVP adjustment (d)	28,252	40,507	40,446	0	109,205
MVP adjustment (10% reduction) (e) = (d)*- 0.1	-2,825	4,051	-4,044	0	-10,920
2023 MIPS Performance Period (excludes QPs) (f) = (d) + (e)	25,427	36,456	36,401	0	98,285
*Currently approved 2022 MIPS performance period (excludes QPs) (g)	29,273	41,340	42,255	0	112,868
Difference (h) = (f) - (g)	-3,846	-4,884	-5,854	0	-14,583

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 76 are not mutually exclusive.

Table 77 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the CY 2022 and 2023 MIPS performance period/2024 and 2025 MIPS payment years. We assume that clinicians that submitted quality data as groups in the CY 2019 MIPS performance period/2021 MIPS payment year will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the CY 2022 and 2023 MIPS performance periods/ 2024 and 2025 MIPS payment years. Specifically, for the CY 2022 MIPS performance period/2024 MIPS payment year we estimate that 11,529 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 243,169 clinicians; 8,127 groups and virtual groups will submit for eCQM collection types on behalf of 249,878 eligible clinicians; and 114 groups will submit data via the CMS Web Interface on behalf of 44,385 clinicians. These are decreases of −75 and −93 respondents from the currently approved estimates of 11,604, and 8,220 groups and virtual groups for the MIPS CQM and QCDR and eCQM collection types, and an increase of +114 groups from the currently approved estimates of 0 groups for the CMS Web Interface collection types, respectively.

As shown in Table 77, for the CY 2023 MIPS performance period/2025 MIPS payment year we estimate that 10,434 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 313,038 clinicians and 7,359 groups and virtual groups will submit for eCQM collection types on behalf of 339,109 eligible clinicians. These are decreases of −1,170 and −861 respondents from the currently approved estimates of 11,604, and 8,220 groups and virtual groups for the MIPS CQM and QCDR and eCQM collection types, respectively. The reason for the difference in estimated number of respondents from the estimates for the CY 2022 MIPS performance period/2024 MIPS payment year describe above, is due to the sunset of the CMS Web Interface as a collection type and the implementation of MVPs beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. As the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities would participate through traditional MIPS and base our estimates on submissions received in the CY 2019 MIPS performance period/2021 MIPS payment year.

TABLE 77: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type on Behalf of Clinicians

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2022 MIPS performance period (excludes QPs) (a)	0	11,529	8,127	114	19,770
*Currently approved 2022 MIPS performance period (excludes QPs) (b)	0	11,604	8,220	0	19,824
Difference (c) = (a) - (b)	0	-75	-93	+114	-54
2023 MIPS performance period (excludes QPs) (d) prior to adjustments	0	11,529	8,127	114	19,770
Adjustment for Web Interface (e)	0	64	50	-114	0
Adjustment for MVPs (10%) (g) = ((d) + (e)) * 0.1	0	-1,159	-817.7	0	-1977
2023 MIPS performance period (excludes QPs) – Adjusted. (h) = (d) + (e) + (f) + (g)	0	10,434	7,359	0	17,793
*Currently approved 2022 MIPS performance period (excludes QPs) (i)	0	11,604	8,220	0	19,824
Difference (j) = (h) - (i)	0	-1,170	-861	0	-2,031

*Currently approved by OMB under control number 0938-1314 (CMS-10621) from the CY 2021 PFS final rule.

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. For the CY 2023 MIPS performance period/2025 MIPS payment year we refer readers to section IV.A.3.b.(4) of the rule for the changes related to MVP and subgroup reporting requirements. In terms of the quality measures available for clinicians and groups to report for the CY 2022 MIPS performance period/2024 MIPS payment year, we are proposing that the total number of quality measures will be 195. The new MIPS quality measures proposed for inclusion in MIPS for the CY 2022 MIPS performance period/2024 MIPS payment year and future years are found in Table Group A of Appendix 1; MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures proposed for removal can be found in Table Group C of Appendix 1. These proposed measures are stratified by collection type in Table 78, as well as counts of new, removed, and substantively changed measures.

TABLE 78: Summary of Proposed Quality Measures for the CY 2022 MIPS Performance Period

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal*	# Measures Proposed with a Substantive Change*	# Measures Remaining for CY 2022*
Medicare Part B Claims Specifications	0	-14	15	33
MIPS CQMs Specifications	+2	-19	67	168
eCQM Specifications	+1	-2	40	46
Survey – CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	0	10	10
Administrative Claims	+2	0	0	4
Total	+5	-19*	+84*	1,195*

*A measure may be specified under multiple collection types but will only be counted once in the total.

For the CY 2022 MIPS performance period/2024 MIPS payment year, we are proposing a net reduction of 15 quality measures across all collection types compared to the 209 measures finalized for the CY 2021 MIPS performance period/2023 MIPS payment year (85 FR 84974). Specifically, as discussed in section IV.A.3.c.(1)(d), we are proposing to add 2 new administrative claims outcome measures, remove 19 quality measures, and make substantive updates to 84 quality measures. We do not anticipate that our proposal to remove these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures. For the change in associated burden related to the proposals introducing MVP and subgroup reporting beginning in the CY 2023 MIPS performance period/2025 MIPS payment year, we refer readers to Table 87 of this section.

(3) Quality Payment Program Identity Management Application Process

This rule is not proposing any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not proposing any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are adjusting our currently approved burden estimates based on more recent data. For the change in associated burden related to the proposals introducing MVP and subgroup reporting beginning in the CY 2023 MIPS performance period/2025 MIPS payment year, we refer readers to Table 87 of this section.

The following proposed burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77501 through 77504), CY 2018 Quality Payment Program final rule (82 FR 53912), CY 2019 PFS final rule (83 FR 60004 through 60005), CY 2020 PFS final rule (84 FR 63124 through 63126) and the CY 2021 PFS final rule (85 FR 84975 through 84976) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 76, based on data from the CY 2019 MIPS performance period/2021 MIPS payment year, we assume that 28,252 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule is proposing to adjust the number of Medicare Part B claims respondents from the currently approved estimate of 29,273 to 28,252 (a decrease of 1,021) based on more recent data and our methodology of accounting only for clinicians in small practices who submitted such claims data in the CY 2019 MIPS performance period/2021 MIPS payment year rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type.

As shown in Table 79, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) for a computer systems analyst at a cost of $14.28 (0.15 hr × $95.22/hr) to 7.2 hours for a computer systems analyst at a cost of $685.58 (7.2 hr × $95.22/hr). The burden will involve becoming familiar with MIPS quality measure specifications.

Consistent with our currently approved per response time figures, we believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $114.24/hr for a medical and health services manager, 1 hour at $217.32/hr for a physician, 1 hour at $48.16/hr for an LPN, 1 hour at $95.22/hr for a computer systems analyst, and 1 hour at $40.02/hr for a billing and posting clerk. We are not revising our currently approved per response time estimates.

As shown in Table 79, considering both data submission and start-up requirements for our adjusted number of clinicians, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time for the CY 2022 MIPS performance period/2024 MIPS payment year ranges from 202,002 hours (7.15 hr × 28,252 clinicians) to 401,178 hours (14.2 hr × 28,252 clinicians). The estimated annual cost (per clinician) ranges from $758 [(0.15 hr × $95.22/hr) + (3 hr × $114.24/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr) + (1 hr × $217.32/hr)] to a maximum of $1,429 [(7.2 hr × $95.22/hr) + (3 hr × $114.24/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr) + (1 hr × $217.32/hr)]. The total annual cost for the CY 2022 MIPS performance period/2024 MIPS payment year ranges from a minimum of $21,407,105 (28,252 clinicians × $758) to a maximum of

$40,372,673 (28,252 clinicians × $1,429).

As shown in Table 79, for purposes of calculating total burden associated with the Claims collection type for the CY 2023 MIPS performance period/2025 MIPS payment year only the maximum burden is used. The decrease in the number of annual respondents results in an estimated total annual time of 361,061 hours (14.2 hr × 25,427 clinicians) for the CY 2023 MIPS performance period/2025 MIPS payment year. Using the currently approved unchanged estimate for cost per respondent, the total annual cost for the CY 2023 MIPS performance period/2025 MIPS payment year is $36,335,692 (25,427 clinicians × $1,429 per respondent).

Table 79 summarizes our proposed estimated range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims for both the CY 2022 and 2023 MIPS performance periods/2024 and 2025 MIPS payment years.

TABLE 79: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden (CY 2022)	Maximum Burden (CY 2023)
# of Clinicians (a)	28,252	28,252	28,252	25,427
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1	1
Annual Hours per Clinician (h) = (b) + (c) + (d) + (e) + (f) + (g)	7.15	8.05	14.2	14.2
Total Annual Hours (i) = (a) * (h)	**202,002**	**227,429**	**401,178**	**361,061**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr @ varying times) (j)	$14.28	$99.98	$685.58	$685.58
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr @ 3 hr) (k)	$342.72	$342.72	$342.72	$342.72
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr @ 1 hr) (l)	$95.22	$95.22	$95.22	$95.22
Cost to Review Measure Specifications (@ LPN's labor rate of $48.16/hr @1 hr) (m)	$48.16	$48.16	$48.16	$48.16
Cost to Review Measure Specifications (@ billing clerk's labor rate of $40.02/hr @ 1 hr) (n)	$40.02	$40.02	$40.02	$40.02
Cost to Review Measure Specifications (@ physician's labor rate of $210.44/hr @ 1 hr) (o)	$217.32	$217.32	$217.32	$217.32
*Total Annual Cost Per Clinician (p) = (j) + (k) + (l) + (m) + (n) + (o)	$758	$843	$1,429	$1,429
***Total Annual Cost (q) = (a) * (p)**	**$21,407,105**	**$23,828,302**	**$40,372,673**	**$36,355,692**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 76, using the unchanged currently approved hours per respondent, we estimate that the burden per respondent for quality data submission using the Medicare Part B Claims collection type would range from $758 to $1,429. The decrease in number of respondents from 29,273 to 28,252 results in a total adjustment of between −7,300 hours (−1,021 respondents × 7.15 hr/respondent) at a cost of −$167,945 (−1,021 respondents × $758/respondent) and −14,499 hours (−1,021 respondents × 14.2 hr/respondent) at a cost of −$1,257,748 (−1,021 respondents × $1,429/respondent). For purposes of calculating total burden associated with the proposed rule as shown in Tables 113, 114, 115, and 116, only the maximum burden is used.

As shown in Table 80, for purposes of calculating total burden associated the CY 2023 MIPS performance period/2025 MIPS payment year only the maximum burden is used. Using the unchanged currently approved hours per respondent, we estimate that the burden per respondent for quality data submission using the Medicare Part B Claims collection type would be $1,429. The decrease in number of respondents from 29,273 to 25,427 results in a total adjustment of −54,616 hours (−25,427 respondents × 14.2 hr/respondent) at a cost of −$5,294,729 (−25,427 respondents × $1,429/respondent).

TABLE 80: Adjusted Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden (CY 2022)	Maximum Burden (CY 2023)
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	209,302	235,648	415,677	415,677
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 79, row (i))	202,002	227,429	401,178	361,061
Difference (c) = (b) - (a)	**-7,300**	**-8,219**	**-14,499**	**-54,616**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$21,575,050	$24,010,973	$41,630,421	41,630,421
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 79, row (q)	$21,407,105	$23,828,302	$40,372,673	$36,335,692
Difference (f) = (e) - (d)	**-$167,945**	**-$182,671**	**-$1,257,748**	**-$5,294,729**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77504 through 77505), CY 2018 Quality Payment Program final rule (82 FR 53912 through 53914), CY 2019 PFS final rule (83 FR 60005 through 60006), CY 2020 PFS final rule (84 FR 63127 through 63128), CY 2021 PFS final rule (85 FR 84977 through 84979) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types. For the change in associated burden for quality data submission related to the proposals introducing MVP and subgroup reporting beginning in the CY 2023 MIPS performance period/2025 MIPS payment year, we refer readers to Table 87.

As noted in Tables 72, 73, and 74, and based on data from the CY 2019 MIPS performance period/2021 MIPS payment year, for the CY 2022 performance period/2024 MIPS payment year, we assume that 279,247 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 52,036 clinicians will submit as individuals and the remaining 279,223 clinicians will submit as members of 11,527 groups and virtual groups. This is an increase of 10,696 individuals and a decrease of 32 groups from the estimates of 41,340 individuals and the 11,559 groups provided in the CY 2021 PFS final rule (85 FR 84977). Given that the number of measures required for clinicians and groups is the same, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data is total of 9 hours at a cost of $922.76 per response. This consists of 3 hours at $95.22/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $114.24/hr for a medical and health services manager, 1 hour at $95.22/hr for a computer systems analyst, 1 hour at $48.16/hr for a LPN, 1 hour at $40.02/hr for a billing clerk, and 1 hour at $217.32/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) at $95.22/hr for a computer systems analyst at a cost of $7.90 (0.083 hr × $95.22/hr). Overall, we estimate 9.083 hr/response (3 hr + 2 hr + 1 hr + 1 hr + 1 hr + 1 hr + 0.083 hr) at a cost of $922.76/response [(3 hr × $95.22/hr) + (2 hr × $114.24/hr) + (1 hr × $217.32/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr) + (0.083 hr × $95.22/hr)].

For the CY 2022 MIPS performance period/2024 MIPS payment year, in aggregate, we estimate a burden of 472,643 hours [9.083 hr/response × (40,507 clinicians submitting as individuals + 11,527 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 52,036 responses)] at a cost of $ $48,016,739 (52,036 responses × $922.76/response).

For the CY 2023 MIPS performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 425,787 hours [9.083 hr/response × (36,456 clinicians submitting as individuals + 10,432 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 46,877 responses)] at a cost of $43,256,221 (46,877 responses × $922.76/response). Based on these assumptions, we have estimated in Table 81 the burden for these submissions.

TABLE 81: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2022 Performance Period	2023 Performance Period
# of clinicians submitting as individuals (a)	40,507	36,456
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	11,527	10,432
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	**52,036**	**46,877**
Hours Per Respondent to Report Quality Data (d)	3	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physician Review Measure Specifications (i)	1	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083	0.083
Annual Hours Per Respondent (k)= (d) + (e) + (f) + (g) + (h) + (i) + (j)	9.083	9.083
Total Annual Hours (l) = (c)*(k)	**472,643**	**425,787**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr) (m)	$285.66	$285.66
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr) (n)	$228.48	$228.48
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr) (o)	$95.22	$95.22
Cost LPN Review Measure Specifications (@ LPN's labor rate of $48.16/hr) (p)	$48.16	$48.16
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $40.02/hr) (q)	$40.02	$40.02
Cost Physician Review Measure Specifications (@ physician's labor rate of $217.32/hr) (r)	$217.32	$217.32
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $95.22/hr) (s)	$7.90	$7.90
*Total Annual Cost Per Respondent (t) = (m) + (n) + (o) + (p) + (q) + (r) + (s)	$922.76	$922.76
***Total Annual Cost (u) = (c) * (t)**	**$48,016,739**	**$43,256,221**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 82, using the unchanged currently approved hours per respondent burden estimate, the decrease of 913 respondents from 52,949 to 52,036 for the CY 2022 MIPS performance period/2024 MIPS payment year results in a decrease of −8,293 hours (−913 respondents × 9.083 hr/respondent) and −$842,483 (913 respondents × $922.76/respondent).

For the CY 2023 MIPS performance period/2025 MIPS payment year, using the unchanged currently approved hours per respondent burden estimate, the decrease of 6,072 respondents from 52,949 to 46,877 results in a decrease of −55,149 hours (−6,072 respondents × 9.083 hr/respondent) and −$5,602,649 (−6,072 respondents × $922.76/respondent).

TABLE 82: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2022 Performance Period	2023 Performance Period
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	480,936	480,936
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 81, row (l))	472,643	425,787
Difference (c) = (b) - (a)	**8,293**	**-55,149**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$48,859,392	$48,859,392
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 81, row (u))	$48,016,909	$43,256,742
Difference (f) = (e) - (d)	**-$842,483**	**-$5,602,649**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), CY 2020 PFS final rule (84 FR 63128 through 63130) and the CY 2021 PFS final rule (85 FR 84979 through 84980) for our previously finalized requirements and burden for quality data submission via the eCQM collection types. For the change in associated burden for quality data submission related to the proposals introducing MVP and subgroup reporting beginning in the CY 2023 MIPS performance period/2025 MIPS payment year, we refer readers to Table 87 of this section.

Based on CY 2019 MIPS performance period/2021 MIPS payment year data, for the CY 2022 MIPS performance period/2024 MIPS payment year, we assume that 322,392 clinicians will elect to use the eCQM collection type; 40,446 clinicians are expected to submit eCQMs as individuals; and 8,127 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 273,819 clinicians. This is a decrease of 2,109 individuals and 27 groups from the estimates of 42,555 individuals and 8,154 groups provided in the CY 2021 PFS final rule (85 FR 84979). We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $95.22/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $114.24/hr for a medical and health services manager, 1 hour at $217.32/hr for a physician, 1 hour at $95.22/hr for a computer systems analyst, 1 hour at $48.16/hr for an LPN, and 1 hour at $40.02/hr for a billing clerk. Overall, we estimate a cost of $812.76/response [(2 hr × $95.22/hr) + (2 hr × $114.24/hr) + (1 hr × $217.32/hr) + (1 hr × $95.22/hr) + (1 hr × $48.16/hr) + (1 hr × $40.02/hr)].

For the CY 2022 MIPS performance period/2024 MIPS payment year, in aggregate, we estimate a burden of 388,584 hours [8 hr × 48.573 (40,446 clinicians + 8,127 groups and virtual groups)] at a cost of $39,812,374 (48,573 responses × $819.64/response). For the CY 2023 MIPS performance period/2025 MIPS payment year, in aggregate, we estimate a burden of 350,186 hours [8 hr × 43,773 (36,401 clinicians + 7,372 groups and virtual groups)] at a cost of $35,878,102 (43,773 responses × $819.64/response). Based on these assumptions, we have estimated in Table 83 the burden for these submissions.

TABLE 83: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

	2022 Performance Period	2023 Performance Period
# of clinicians submitting as individuals (a)	40,446	36,401
# of Groups submitting via EHR on behalf of individual clinicians (b)	8,127	7,372
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	48,573	43,773
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physicians Review Measure Specifications (i)	1	1
Annual Hours Per Respondent (j) = (d) + (e) + (f) + (g) + (h) + (i)	8	8
Total Annual Hours (k) = (c) * (j)	**388,584**	**350,186**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr) (l)	$190.44	$190.44
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr) (m)	$228.48	$228.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr) (n)	$95.22	$95.22
Cost to Review Measure Specifications (@ LPN's labor rate of $48.16/hr) (o)	$48.16	$48.16
Cost to Review Measure Specifications (@ clerk's labor rate of $40.02/hr) (p)	$40.02	$40.02
Cost to Review Measure Specifications (@ physician's labor rate of $217.32/hr) (q)	$217.32	$217.32
*Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$819.64	$819.64
***Total Annual Cost (s) = (c) * (r)**	**$39,812,374**	**$35,878,102**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 84, using the unchanged currently approved hours per respondent burden estimate, the decrease of 1,897 respondents from 50,470 to 48,573 for the CY 2022 MIPS performance period/2024 MIPS payment year results in a total difference of −15,176 hours at a cost of −$1,544,857. For CY 2023 MIPS performance period/2025 MIPS payment year, using the unchanged currently approved hours per respondent burden estimate, the decrease of 6,697 respondents from 50,470 to 43,773 results in a total difference of −53,574 hours at a cost of −$5,488,883.

TABLE 84: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

	2022 Performance Period	2023 Performance Period
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	403,760	403,760
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 83, row (k))	388,584	350,186
Difference (c) = (b) - (a)	**-15,176**	**-53,574**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$41,367,231	$41,367,231
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 83, row (s))	$39,812,374	$35,878,348
Difference (f) = (e) - (d)	**-$1,544,857**	**-$5,488,883**

(7) ICRs Regarding Burden for MVP Reporting

Section IV.A.3.b.(2)(d) of this rule describes proposals related to implementing MVPs beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. The MVPs would include the Promoting Interoperability performance category as a foundational element and incorporate population health claims-based measures, as feasible, along with the relevant measures and activities in the quality, cost and improvement activities performance categories. For the CY 2023 MIPS performance period/2025 MIPS payment year, CMS is proposing an inventory of seven MVPs included in Appendix 3: MVP Inventory of this rule to assess performance across MVPs for the quality, cost, improvement activities, and Promoting Interoperability performance categories. Additionally, in section IV.A.3.b.(2)(c)(i) of this rule, we propose to use the term ''MVP Participant'' to refer to clinicians who would choose to participate in MIPS for reporting MVPs.

The following new ICRs reflect the burden associated with the first year of data collection related to the proposed implementation of MVPs and subgroup reporting in the CY 2023 MIPS performance period/2025 MIPS payment year as described in section IV.A.3.b.(2)(d) of this rule. The proposed requirements and burden associated with the implementation of MVPs and subgroups will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

While MVP respondents report on all performance categories, we believe that for purposes of data submission, the burden for clinicians submitting information for the Promoting Interoperability and improvement activities performance categories of MVPs will be consistent with the currently approved estimated burden per respondent for clinicians submitting data for these performance categories in traditional MIPS. We acknowledge that clinicians participating through MVPs will have fewer requirements to meet for the improvement activity performance category as discussed in section IV.A.3.b.(4)(d)(iv) of this proposed rule. We assume that these requirement changes will not significantly lower the burden for clinicians reporting MVPs. Therefore, we will not add additional ICRs to capture the burden for the Promoting Interoperability and Improvement Activity performance categories. For this rule, we are proposing to create a separate ICR for estimating the burden associated with data submission for the Quality performance category of MVPs. We considered whether we should have a separate ICR to estimate burden for submission of measures and activities in the Promoting Interoperability performance category of MVPs. Based on our assumption above that the burden for clinicians submitting information for these performance categories of MVPs will be consistent with the currently approved estimated burden per respondent for clinicians submitting data in traditional MIPS, we anticipate that the separate ICRs would not be of value to clinicians.

We seek comment on our proposal to distinctly estimate burden only for data submission in the Quality performance category of MVPs and whether we should revise the MVP submission ICR to include all the four MIPS performance categories and whether our assumptions on Promoting Interoperability and Improvement Activities should be modified for MVPs.

(a) Burden for MVP Quality Submission

In section IV.A.3.b.(2)(d)(i) of this rule, we propose to implement voluntary MVP reporting beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. If this proposal is finalized, clinicians participating in MIPS would have the option to voluntarily submit data using MVPs starting with the CY 2023 MIPS performance period/2025 MIPS payment year. While we recognize the implementation of MVPs in MIPS will result in a burden for registration, we also assume that MVP reporting will result in a decline in burden for MVP participants due to proposed changes in the MVP reporting requirements described in section IV.A.3.b.(4)(d) of this rule. We anticipate that the clinicians choosing to participate in MIPS for reporting MVPs would need to select from a reduced inventory of measures and activities for the quality and improvement activities performance categories. This reduction in burden is described in the quality, improvement activities and Promoting Interoperability performance categories sections below.

For the ICRs related to MVP participants, we used the MIPS submission data from the CY 2021 MIPS performance period/2023 MIPS payment year. Based on our review of the proposed inventory of 7 MVPs in Appendix 3: MVP Inventory of this rule and the existing submission trends in MIPS for the measures and activities included in these MVPs, we anticipate that 10 percent of the clinicians who participate in traditional MIPS in the CY 2022 MIPS performance period/2024 MIPS payment year will report MVPs in the CY 2023 MIPS performance period/2025 MIPS payment year. Given that MVPs are new, voluntary, and represent a reduction in burden per response, we believe that we should be conservative

in estimating the number of clinicians submitting through MVPs during the initial year. Given that MVPs are a new mechanism available for clinicians, we believe that initial participation numbers will be relatively low. In an effort to be conservative in our estimate of burden reduction due to MVP reporting and reflect the anticipate low uptake by clinicians in the first year of MVP availability, we assume that a total of 10 percent of MIPS submitters will become MVP participants in the CY 2023 MIPS performance period/2025 MIPS payment year.

As described in section IV.A.3.b.(2)(d)(ii) of this rule, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, we are proposing voluntary subgroup reporting within MIPS limited to clinicians reporting the MVP or the APP. We recognize the implementation of subgroups for clinicians to participate in MVP and APP reporting in MIPS will result in additional burden. We believe that subgroup participation option would allow clinicians in certain specialties and subspecialties to report on measures and activities meaningful to the scope of care provided. We anticipate that public reporting of subgroup performance information would allow patients to identify clinicians in multispecialty groups that are representative of the care specific to their clinical condition. Clinician participation in subgroups is new to MIPS and we do not have any historical participation data to estimate the submission burden for clinicians who would choose to participate as subgroups for reporting the MVP or the APP. We refer readers to section IV.A.3.b.(3) of this proposed rule for details on the proposals related to subgroup composition.

We anticipate that the subgroup reporting option would increase reporting and allow clinicians in specialties to report on measures and activities meaningful to their practice. Due to the delay in implementation of subgroup reporting in the CY 2023 MIPS performance period/2025 MIPS payment year, we anticipate that there is an adequate amount of time for clinicians that historically participate in MIPS to determine if they would be able to participate as subgroups for reporting on the measures and activities in an MVP. However, due to the limited number of MVPs available for clinicians to choose, the additional burden involved in reporting, and also given the voluntary option to participate as subgroups for reporting the MVPs or the APP, we anticipate that a relatively small number of clinicians would choose to participate as subgroups in the CY 2023 MIPS performance period/2025 MIPS payment year. Therefore, we assume there will be 20 subgroups reporters in the CY 2023 MIPS performance period/2025 MIPS payment year. We assume that more clinicians will choose to participate as subgroups in future years. We seek comment on our MVP and subgroup reporting assumptions for the CY 2023 MIPS performance period/2025 MIPS payment year.

(i) Burden for MVP Registration: Individuals, Groups and APM Entities

Beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, we propose that clinicians interested in participating in MIPS through MVP reporting would be required to complete an annual registration process described in section IV.A.3.b.(4)(f) of this rule. At the time of registration, MVP participants would need to select a specific MVP, a population health measure and if administrative claims measures are included in the selected MVP, the MVP participants would also need to choose an applicable administrative claims measure in the MVP. We refer readers to section IV.A.3.b.(4)(f) of this rule for additional details on MVP registration requirements.

Due to the delay in implementation of MVPs in the CY 2023 MIPS performance period/2025 MIPS payment year, we anticipate that there is an adequate amount of time for clinicians that historically participate in MIPS to determine if the measures and activities in an MVP are applicable to the scope of care provided. In Table 85, we estimate that the registration process for clinicians choosing to submit MIPS data for the measures and the activities in an MVP would require 0.25 hours of a computer systems analyst's time, similar to the currently approved burden of group registration process for CMS Web Interface finalized in the CY 2021 PFS final rule (85 FR 84983) for the CY 2023 MIPS performance period/2025 MIPS payment year. We assume that the staff involved in the MVP registration process will mainly be computer systems analysts or their equivalent, who have an average labor cost of $95.22/hour.

As discussed above, based on data from the CY 2019 MIPS performance period/2021 MIPS payment year, we assume that approximately 10 percent of the clinicians that currently participate in MIPS will submit data for the measures and activities in an MVP. Note that we apply this 10 percent calculation after adding the clinicians who begin submitting though the CQM and eCQM collection types due to the proposed sunset of Web Interface in the CY 2023 MIPS performance period/2025 MIPS payment year. For the CY 2023 MIPS performance period/2025 MIPS payment year, we assume that a total of 25,798 submissions would be received for the measures and activities included in MVPs. This total includes our estimate of 20 subgroup reporters that will also be reporting MVPs in addition to MVP reporters who currently participate in MIPS. Therefore, we assume that the total number of individual clinicians, groups, subgroups and APM Entities to complete the MVP registration process is 12,918. We estimate that the total cost to clinicians participating as individuals and groups associated with the MVP registration process will be approximately $307,513. Table 85 includes our burden assumptions related to the MVP registration process for clinicians participating in MIPS for reporting MVPs as individuals, groups, subgroups, and APM Entities.

TABLE 85: Total Estimated Burden for MVP Registration (Individual clinicians, Groups, Subgroups and APM Entities)

	Burden Estimate
Estimated # of Individual clinicians, groups, subgroups and APM Entities Registering (a)	12,918
Estimated Total Annual Burden Hours Per Registration (b)	0.25
Estimated Total Annual Burden Hours for MVP Registration (c) = (a) * (b)	**3,230***
Estimated Cost Per MVP (@ computer systems analyst's labor rate of $95.22/hr. (d)	95.22
Estimated Total Annual Burden Cost for MVP Registration (e) = (c) * (d)	**$307,513***

*Due to burden being estimated in fractions of minutes and hours, totals may reflect impact of rounding.

(ii) Burden for Subgroup Registration

We propose to add a separate ICR to estimate the burden associated with subgroup registration to capture the proposed subgroup registration requirements in section IV.A.3.b.(4)(f)(ii)(D) of this rule. In section IV.A.3.b.(3)(c)(ii) of this rule, we propose to define a subgroup at § 414.1305 as a subset of a group, as identified by a combination of the group TIN, the subgroup identifier, and each eligible clinician's NPI. In addition to the burden for MVP registration process described above, clinicians who choose to form subgroups for reporting the MVPs or the APP would need to submit a list of each TIN/NPI associated with the subgroup and a plain language name for the subgroup in a manner specified by CMS, described in section IV.A.3.b.(4)(f)(ii)(D) of this rule.

As discussed above, we estimate that clinicians would choose to form 20 subgroups for reporting the measures and activities in MVPs. Additionally, we estimate that clinicians who choose to participate as subgroups for reporting MVPs would require a minimum of 0.5 hours per subgroup respondent to submit the proposed requirements for subgroup registration. We assume that the staff involved in the subgroup registration process will mainly be computer systems analysts or their equivalent, who have an average labor cost of $95.22/hr.

As all subgroups will report MVPs, the burden associated with subgroup quality reporting will be included with the MVP quality reporting ICR. Burden associated with subgroup submissions for Promoting Interoperability and improvement activities will be included with those ICRs.

TABLE 86: Total Estimated Burden for Subgroup Registration CY 2023 MIPS Performance Period/2025 MIPS payment year

	Burden Estimate
Estimated # of Subgroups Registering(a)	20
Estimated Total Annual Burden Hours Per Subgroup (b)	0.5
Estimated Total Annual Burden Hours for Subgroup Reporting (c) = (a) * (b)	**10**
Estimated Cost Per Subgroup (@ computer systems analyst's labor rate of $95.22/hr. (d)	$95.22
Estimated Total Annual Burden Cost for Subgroup Registration (e) = (a) * (d)	**$952**

(iii) Burden for MVP Quality Performance Category Submission

In the CY 2017 PFS final rule (81 FR 77100 through 77114), we established the submission criteria for quality measures (excluding the CMS Web Interface measures and the CAHPS for MIPS survey measure) at § 414.1335, which requires a MIPS eligible clinician, group, or virtual group that is reporting on Qualified Clinical Data Registry (QCDR) measures, MIPS clinical quality measures (MIPS CQMs), electronic CQMs (eCQMs), or Medicare Part B claims measures to submit data on at least six measures, including at least one outcome measure. As discussed in section IV.A.3.b.(4)(d)(ii) of this proposed rule, we propose that except as provided in paragraph

§ 414.1365(c)(1)(i), an MVP Participant must select and report 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure, included in the MVP. The decrease in the number of required measures in the quality performance category from 6 to 4 is a two-thirds reduction in the number of measures needed for eligible clinicians to submit data for the quality performance category in MVPs described in Appendix 3: MVP Inventory of this proposed rule. Therefore, we estimate that the time for submitting the measures in the MVP quality performance category will, on average, take two-thirds of the currently approved burden per respondent for the quality performance category as it does to complete a MIPS quality submission through the CQM, eCQM, and Claims submission types.

As described above in this section of the proposed rule, we estimate that 10 percent of the clinicians who participated in MIPS for the CY 2019 MIPS performance period/2021 MIPS payment year would submit data for the quality performance category of MVPs beginning with the CY 2023 MIPS performance period/2025 MIPS payment year. We anticipate that there will be 20 subgroups reporters in the CY 2023 MIPS performance period/2025 MIPS payment year. As shown in Table 87, we estimate that approximately 2,825 clinicians would submit data for the MVP quality performance category using the Medicare Part B claims collection type; approximately 5,210 clinicians and 10 subgroups will submit data using MIPS CQM and QCDR collection type; and approximately 4,862 clinicians and 10 subgroups will submit data using eCQMs collection type. We want to note that we used the same methodologies used in sections V.B.8.e.(4), V.B.8.e.(5) and V.B.8.e.(6) to estimate the quality submission burden for each collection type. As shown in Table 87, for the clinicians and subgroups submitting data for the MVP quality performance category, we estimate a burden of 26,670 hours (9.44 hr × 2,825 clinicians) at a cost of $2,691,329 (2,825 respondents × 952.68/respondent) for the Medicare Part B claims collection type, 31,163 hours [5.97 hr × 5,220 (5,210 + 10)] at a cost of $3,211,216 (5,220 × 615.18/respondent) for the MIPS CQM and QCDR collection type, and 25,822 hours [5.3 hr × 4,872 (4,862 + 10) respondents] at a cost of $2,662,191 (4,872 × 546.43/respondent) for the eCQM collection types.

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TABLE 87: Estimated Burden for Quality Performance Category: Clinicians Submitting Data for MVPs in CY 2023

	eCQM Collection Type	CQM and QCDR Collection Type	Claims Collection Type
# of Submissions from pre-existing collection types (a)	4,862	5,210	2,825
# of Subgroup reporters (b)	10	10	0
Total MVP participants (c) = (a) + (b)	4,872	5,220	2,825
Hours Per Clinician to Submit Quality Data (d)	1.33	2	4.8
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	1.33	1.33	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	0.66	0.66	0.66
# of Hours LPN Review Measure Specifications (g)	0.66	0.66	0.66
# of Hours Billing Clerk Review Measure Specifications (h)	0.66	0.66	0.66
# of Hours Physician Review Measure Specifications (i)	0.66	0.66	0.66
Annual Hours per Clinician Submitting Data for MVPs (j) = (d) + (e) + (f) + (g) + (h) + (i)	5.3	5.97	9.44
Total Annual Hours (k) = (c) * (j)	**25,822**	**31,163**	**26,688**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $95.22/hr @ varying times) (k)	$126.64	$190.44	$457.06
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $114.24/hr) (l)	$151.94	$151.94	$228.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $95.22/hr) (m)	$62.85	$62.85	$62.85
Cost to Review Measure Specifications (@ LPN's labor rate of $48.16/hr) (n)	$31.79	$31.79	$31.79
Cost to Review Measure Specifications (@ billing clerk's labor rate of $40.02/hr) (o)	$26.41	$26.41	$26.41
Cost to Review Measure Specifications (@ physician's labor rate of $217.32/hr) (p)	$144.88	$144.88	$144.88
*Total Annual Cost Per Clinician (q) = (k) + (l) + (m) + (n) + (o) + (p)	$546.43	$615.18	$952.68
***Total Annual Cost (r) = (c) * (q)**	**$2,662,191**	**$3,211,216**	**$2,691,329**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

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(8) Quality Data Submission via CMS Web Interface

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Background

In the CY 2021 PFS final rule, we finalized our policy to sunset the CMS Web Interface measures as a collection type/submission type starting with the CY 2022 MIPS performance period/2024 MIPS payment year. As a result of this provision, for the CY 2022 MIPS performance period/2024 MIPS payment year, we estimated a burden of zero due to our assumption that all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types (85 FR 84981).

In section IV.A.3.d.(1)(d) of this rule, we are proposing to continue the CMS Web Interface measures as a collection type for the CY 2022 MIPS performance period/2024 MIPS payment year. Additionally, we are proposing to sunset the CMS Web Interface measures as a collection type for the CY 2023 MIPS performance period/2025 MIPS payment year. For this proposed rule, we are providing a burden estimate for the CY 2022 and CY 2023 MIPS performance periods/2024 and 2025 MIPS payment years.

For the CY 2022 MIPS performance period/2024 MIPS payment year, we assume that 114 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the CY 2019 MIPS performance period/2021 MIPS payment year. This is an increase of 114 groups from the currently approved number of 0 groups provided in the CY 2021 PFS final rule (85 FR 84981 due to the proposal to continue with the CMS Web Interface as a collection type for the CY 2022 MIPS performance period/2024 MIPS payment year. We estimate that 44,385 clinicians will submit as part of groups via this method, an increase of 44,385 from our currently approved estimate of 0 clinicians.

The proposed estimated burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's

beneficiaries that is prepopulated in the CMS Web Interface. Our proposed burden estimate for submission includes the time (61 hours and 40 minutes or 61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate a burden for the CY 2022 MIPS performance period/2024 MIPS payment year of 7,030 hours (114 groups × 61.67 hr) at a cost of $669,432 (114 groups × $5,872.21/group). For the CY 2023 MIPS performance period/2025 MIPS payment year, we propose to revise our estimated burden to zero due to our assumption that with the proposed policy to sunset the CMS Web Interface as a collection type, all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types. Based on the assumptions discussed in this section, Table 88 summarizes the proposed estimated burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 88: Estimated Burden for Quality Data Submission via the CMS Web Interface

	CY 2022 MIPS Performance Period	CY 2023 MIPS Performance Period
# of Eligible Group Practices (a)	114	0
Total Annual Hours Per Group to Submit (b)	61.67	0
Total Annual Hours (c) = (a) * (b)	7,030	0
Cost Per Group to Report (@ computer systems analyst's labor rate of $95.22/hr) (d) = ($95.22/hr) * (b)	$5,872.21	0
Total Annual Cost (e) = (a) * (d)	$669,433	0

TABLE 89: Change in Estimated Burden for Quality Data Submission via the CMS Web Interface

	CY 2022 MIPS Performance Period	CY 2023 MIPS Performance Period
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	0	0
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 88, row (c))	7,030	0
Difference (c) = (b)-(a)	**+7,030**	**0**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$0	0
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 88, row (e))	$669,433	0
Difference (f) = (e)-(d)	**+$669,433**	**0**

(9) Beneficiary Responses to CAHPS for MIPS Survey

This rule does not propose any new or revised collection of information requirements or burden related to the CAHPS for MIPS survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any changes under that control number.

(10) Group Registration for CMS Web Interface

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2021 PFS final rule, we finalized to sunset the CMS Web Interface measures as a collection type/submission type starting with the CY 2022 MIPS performance period/2024 MIPS payment year. As a result, we estimated that there would be zero hours and $0 burden for group registration for the CMS Web Interface for the CY 2022 MIPS performance period/2024 MIPS payment year (85 FR 84984). As discussed in section IV.A.3.d.(1)(d) of this proposed rule, we are proposing to continue the CMS Web Interface measures as a collection type for the CY 2022 MIPS performance period/2024 MIPS payment year. We are also proposing to sunset the CMS Web Interface as a collection type starting with the CY 2023 MIPS performance period/2025 MIPS payment year.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an online registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 90, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $95.22/hr for a computer

systems analyst (or their equivalent) to register the group.

Because we are finalizing to sunset the CMS Web Interface beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, it is possible that fewer groups will elect to register to submit quality data for the first time in the performance year prior to the collection type/submission type no longer being available; however, we currently have no data with which to estimate what the associated reduction may be. Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84983), we continue to assume that approximately 90 groups will elect to use the CMS Web Interface for the first time during the CY 2022 MIPS performance period/2025 MIPS payment year based on the estimated number of new registrations during the CY 2021 MIPS performance period/2023 MIPS payment year. As shown in Table 90, we estimate a burden of 22.5 hours (90 new registrations × 0.25 hr/registration) at a cost of $2,142 (22.5 hr × $95.22/hr).

TABLE 90: Estimated Burden for Group Registration for CMS Web Interface

	Burden Estimate
Number of New Groups Registering for CMS Web Interface (a)	90
Annual Hours Per Group (b)	0.25
Total Annual Hours (c) = (a) * (b)	22.5
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (a) * (d)	$2,142

As shown in Table 91, the proposed estimated increase in the number of groups registering for the CMS Web Interface collection type to submit the MIPS data and the estimated increase in burden per respondent results in adjustment to the total time burden of +22.5 hours (+90 respondents × 0.25 hr/respondent) at a cost of $2,142 for the CY 2022 MIPS performance period/2024 MIPS payment year. For the CY 2023 MIPS performance period/2025 MIPS payment year, our proposed burden estimate is $0.

TABLE 91: Change in Estimated Burden for Group Registrations for the CMS Web Interface

	CY 2022Performance Period	CY 2023 Performance Period
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	0	0
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (See Table 90, row (c))	22.5	0
Difference (c) = (b) - (a)	**+22.5**	**0**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	0	0
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (See Table 90, row (e))	$2,142	0
Difference (f) = (e) - (d)	**+2,142**	**0**

(11) Group Registration for CAHPS for MIPS Survey

This rule is not proposing any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not proposing any changes under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

This rule is not proposing any new or revised collection of information requirements or burden related to the call for MIPS quality measures. However, outside of the rulemaking process we are replacing the existing tool for stakeholders beginning with the 2021 Annual Call for Measures. To account for the updated tool (MERIT), we are proposing to revise our currently approved burden estimates. The updated tool and revised burden will be submitted to OMB under control number 0938–1314 (CMS–10621).

Beginning with the 2021 Annual Call for Measures, we replaced the customary Office of the National Coordinator (ONC) Issue Tracking System Jira platform that stakeholders used to submit candidate quality measure specifications and all supporting data files for CMS review with the MUC Entry/Review Information Tool (MERIT). For the ONC Issue Tracking System Jira platform used by stakeholders, the approved estimated time for a practice

administrator to identify, propose, and link to a quality measure is 0.9 hours and for a clinician to identify, propose, link to quality measure, and complete the Peer Review Journal Article form is 4.6 hours (0.6 hours to identify, propose, and link to quality measure (84 FR 63132) and 4 hours to complete the Peer Review Journal Article Form (84 FR 63133), with a total estimated time of 5.5 hours per quality measure submission. Based on the stakeholder experience with the updated tool and additional information collected at the time of submission, we estimate that it would add approximately 1.5 hours for the practice administrator at $114.24/hr and 0.5 hours at $217.32/hr for a clinician to identify, propose, and link the quality measure, and reduce approximately 2 hours at $217.32/hr for a clinician to complete the Peer Review Journal Article Form, resulting in a new estimated time of 2.4 hours for a practice administrator and 3.1 hours for a clinician, and an unchanged total estimated time of 5.5 hours per quality measure submission. In order to account for the implementation of the MERIT tool starting with the 2021 Annual Call for Measures, we propose to revise the estimated time required for a practice administrator to identify, propose, and link to a quality measure to 2.4 hours (from 0.9 hr) and a clinician to identify, propose, link to quality measure, and complete the Peer Review Journal Article Form to 3.1 hours (from 4.6 hr), resulting in a total estimated time of 5.5 hours per quality measure submission. Based on the number of submissions received during the CY 2020 Call for Quality Measures process, we anticipate receiving the same number of 28 submissions during the CY 2021 Call for Quality Measures process (84 FR 63132).

Although the total estimated time of 5.5 hours for completing a quality measure submission using the MERIT tool (see Table 92) is the same estimated time as the ONC Issue Tracking System Jira platform, we need to account for the changes to the individual components of the estimated time required by a practice administrator and clinician using the MERIT tool. Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84984), we estimate an annual burden of 154 hours (28 submissions × 5.5 hr/measure). Thus, we are proposing to adjust our estimated annual burden from $30,197 (28 submissions × [(0.9 hr × $110.74/hr) + (4.6 hr × $212.78/hr)) to $26,541 (28 measures × [(2.4 hr × $114.24/hr) + (3.1 hr × $217.32/hr)]) a difference of −$3,656.

TABLE 92: Estimated Burden for Call for Quality Measures

	Burden estimate
# of New Quality Measures Submitted for Consideration (a)	28
# of Hours per Practice Administrator to Identify, Propose and Link Measure (b)	2.4
# of Hours per Clinician to Identify and Link Measure (c)	1.1
# of Hours per Clinician to Complete Peer Review Article Form (d)	2
Annual Hours Per Response (e) = (b) + (c) + (d)	5.5
Total Annual Hours (f)=(a)*(e)	**154**
Cost to Identify and Submit Measure (@ practice administrator's labor rate of $114.24/hr) * 2.4 hr = (g)	$274.20
Cost to Identify Quality Measure and Complete Peer Review Article Form (@ clinician's labor rate of $217.32/hr) * 3.1 hr = (h)	$673.69
Total Annual Cost Per Submitted Measure (i)	$947.89
***Total Annual Cost (j)=(a)*(i)**	**$26,541**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the CY 2022 MIPS performance period/2024 MIPS payment year, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis, and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), CY 2019 PFS final rule (83 FR 60011 through 60012), CY 2020 PFS final rule (84 FR 63134 through 63135), and the CY 2021 PFS final rule (85 FR 84984 through 84985) for our previously finalized requirements and burden for reweighting applications for Promoting

Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting for the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

Table 93 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception or as a result of a decertification of an EHR. Based on the number of reweighting applications received by March, 2021 for the CY 2020 MIPS performance period/2022 MIPS payment year, we assume 20,192 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship or EHR decertification and an additional 22,635 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activities performance categories due to an extreme or uncontrollable circumstance. For the CY 2022 MIPS performance period/2024 MIPS payment year, we estimate that a total of 42,797 reweighting applications would be submitted. This is a decrease of 9,302 respondents compared to our currently approved estimate of 52,099 respondents (85 FR 84984). This decrease is likely due to the proposal in section IV.A.3.e.(2)(b)(iii)(A) of this rule to automatically reweight the Promoting Interoperability performance category for small practices who previously had to apply for reweighting. For the CY 2020 MIPS performance period/2024 MIPS payment year, 13,894 respondents requested reweighting due to significant hardship for small practices. Similar to the data used to estimate the number of respondents in the CY 2021 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. We assume that, out of our total respondent count of 42,797 above, we estimate that 22,605 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR.

In the CY 2021 PFS final rule (85 FR 84984) we discussed that, beginning with the CY 2019 MIPS performance period/2021 MIPS payment year, APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. As discussed above in this section of this proposed rule, due to data limitations and our inability to determine who would use the APP versus the traditional MIPS submission mechanism for the 2022 MIPS performance period/2024 MIPS payment year, we assume ACO APM Entities will submit data through the APP and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the 2020 MIPS performance period/2022 MIPS payment year and elected not to report quality data. Based on this data, we estimate that 30 APM Entities will submit an extreme and uncontrollable circumstances exception application for the CY 2022 MIPS performance period/2024 MIPS payment year. Combined with our aforementioned estimate of 42,797 eligible clinicians and groups, the total estimated number of respondents for the CY 2022 MIPS performance period/2024 MIPS payment year is 42,827.

Consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84984–84985), we continue to estimate it will take 0.25 hours for a computer system analyst to complete and submit the application. As shown in Table 93, we estimate an annual burden of 10,707 hours (42,827 applications × 0.25 hr/application) and $1,019,521 (10,707 hr × $95.22/hr).

TABLE 93: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden Estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	42,797
# APM Entities requesting Extreme and Uncontrollable Circumstances exception (b)	30
Total Applications Submitted (c)	42,827
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e) = (a) * (c)	**10,707**
Labor Rate for a computer systems analyst (f)	$95.22/hr
Total Annual Cost (g) = (a) * (f)	**$1,019,521**

As shown in Table 94, using our currently approved burden estimates, the proposed decrease in the estimate number of respondents (from 52,099 to 42,827 respondents) results in an adjustment of minus 2,318 hours (9,272 respondents x 0.25 hr/respondent) and minus $184,747.

TABLE 94: Adjusted Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	13,025
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 93, row (e))	10,707
Difference (c) = (b) - (a)	**-2,318**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$1,204,268
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 93, row (g))	$1,019,521
Difference (f) = (e) - (d)	**-184,747**

(3) Submitting Promoting Interoperability Data

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509 through 77511), CY 2018 Quality Payment Program final rule (82 FR 53919 through 53920), CY 2019 PFS final rule (83 FR 60013 through 60014), CY 2020 PFS final rule (84 FR 63135 through 63137), and the CY 2021 PFS final rule (85 FR 84985 through 84987) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

We did not propose any changes to our current criteria for automatic reweighting of the Promoting Interoperability performance category for certain MIPS eligible clinicians or MIPS eligible clinicians who have experienced a significant hardship or decertification of an EHR. In section IV.A.3.d.(4)(d)(ii) of this proposed rule, we proposed the additional requirement that MIPS eligible clinicians must attest to conducting an annual assessment of the High Priority Guides of the SAFER Guides beginning with the 2022 performance period. Clinicians will complete this attestation by checking a box when they submit their promoting interoperability performance category data. We estimate that this requirement will add an additional minute to the time it takes to complete the submission of promoting interoperability data. We also proposed to modify the Provide Patients Electronic Access to Their Health Information measure to require MIPS eligible clinicians to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely. The proposed requirement would apply beginning with the performance period in 2022, and would include all patient health information from encounters on or after January 1, 2016. We do not believe this proposal will impact the burden of Promoting Interoperability data submission. Therefore, we are not revising the currently approved burden per respondent estimate.

As shown in Table 95, based on data from the CY 2019 MIPS performance period/2021 MIPS payment year, we estimate that a total of 51,647 respondents consisting of 40,172 individual MIPS eligible clinicians and 11,475 groups and virtual groups will submit Promoting Interoperability data. Since our CY 2021 PFS final rule estimated 53,636 respondents, this represents a decrease of 1,989 respondents (51,647 respondents − 53,636 active respondents).

We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APP. As a result, we do not anticipate any change in burden. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 through 59823). Burden estimates for this proposed rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

TABLE 95: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians in CY 2022

	# of Respondents
Number of individual clinicians to submit Promoting Interoperability (a)	40,172
Number of groups to submit Promoting Interoperability (b)	11,475
Total Respondents in 2022 MIPS performance period (CY 2022 PFS Proposed Rule) (c) = (a) + (b)	51,647
*Total Respondents in 2021 MIPS performance period (CY 2021 PFS Final Rule) (d)	53,636
Difference (e) = (c) – (d)	-1,989

As discussed in section IV.A.3.b.(2)(d)(ii) of this proposed rule, we will be introducing subgroup reporting in CY 2023 MIPS performance period/2025 MIPS payment year. As we discussed above in this section of the proposed rule, we estimate that there will be 20 subgroup submissions in CY 2023 MIPS performance period/2025 MIPS payment year, each of which will have burden related to the submission of Promoting Interoperability data. We have included this burden in Table 96.

TABLE 96: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians in CY 2023

	# of Respondents
Number of individual clinicians to submit Promoting Interoperability in CY 2023 (a)	40,172
Number of groups to submit Promoting Interoperability in CY 2023 (b)	11,475
# of Subgroups to submit Promoting Interoperability in MVPs during the CY 2023 MIPS performance period (c)	20
Total Respondents in 2023 MIPS performance period (CY 2022 PFS Proposed Rule) (d) = (a) + (b) + (c)	51,667
*Total Respondents in 2021 MIPS performance period (CY 2021 PFS Final Rule) (e)	53,636
Difference (f) = (d) – (e)	-1,969

With the inclusion of the additional minute (0.02 hr) to attest to conducting an annual assessment of the High Priority Guides of the SAFER Guides, we are proposing to update our estimate of the time required for an individual or group to submit Promoting Interoperability data from 2.67 hours to 2.69 hours (2.67 hr + 0.02 hr). As shown in Table 97, the total burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 138,930 hours (51,647 respondents × 2.69 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,228,915 (138,930 hr × $95.22/hr)).

TABLE 97: Estimated Burden for Promoting Interoperability Performance Category Data Submission in CY 2022

	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	40,172
Number of groups to submit Promoting Interoperability (b)	11,475
Total (c) = (a) + (b)	51,647
Total Annual Hours Per Respondent (d)	2.69
Total Annual Hours (e) = (c) * (d)	**138,930**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (f)	$95.22/hr
Total Annual Cost (g) = (e) * (f)	**$13,228,915**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 98, with the introduction of subgroup reporting in CY 2023 MIPS performance period/2025 MIPS payment year, the total proposed burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 138,984 hours (51,667 respondents × 2.69 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,234,078 (138,984 hr × $95.22/hr)).

TABLE 98: Estimated Burden for Promoting Interoperability Performance Category Data Submission in CY 2023

	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	40,172
Number of groups to submit Promoting Interoperability (b)	11,475
Number of subgroups to submit Promoting Interoperability (c)	20
Total (d) = (a) + (b) + (c)	51,667
Total Annual Hours Per Respondent (e)	2.69
Total Annual Hours (f) = (d) * (e)	**138,984**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (g)	$95.22/hr
Total Annual Cost (h) = (f) * (g)	**$13,234,078**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

Table 99, using our updated per respondent burden estimate (+0.02 hr/response), the decrease in number of respondents and proposed SAFER guide attestation requirement results in a total adjustment of −4,099 hours at a cost of −$390,338 for the CY 2022 MIPS performance period/2024 MIPS payment year and −4,045 hours at a cost of −$385,175 for the CY 2023 MIPS performance period/2025 MIPS payment year.

TABLE 99: Adjusted Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate 2022 MIPS Performance Period	Burden Estimate 2023 MIPS Performance period
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	143,029	143,029
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 98, row (f))	138,930	138,984
Difference (c) = (b) - (a)	**-4,099**	**-4,045**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$13,619,253	$13,619,253
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 98, row (h))	$13,228,915	$13,234,078
Difference (f) = (e) - (d)	**-$390,338**	**-$385,175**

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not proposing any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

i. ICR Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

The following proposed requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512), CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922), CY 2019 PFS final rule (83 FR 60015 through 60017), CY 2020 PFS final rule (84 FR 63138 through 63140) and the CY 2021 PFS final rule (85 FR 84987 through 84989) for our previously finalized requirements and burden for submission of data for the improvement activities performance category.

In section IV.A.3.d.(3) of this rule, we are proposing to: (1) Revise group reporting requirements for the 50 percent threshold to address subgroups; (2) add 7 new improvement activities, modify 15 existing improvement activities, and remove 6 previously adopted improvement activities for the CY 2022 MIPS performance period/2024 MIPS payment year and future years; (3) revise the ''Drug Cost Transparency to include requirements for use of real-time benefit tools'' improvement activity; and (4) add the COVID–19 ''Clinical Data Reporting with or without Clinical Trial'' improvement activity for CY 2022 MIPS performance period/2024 MIPS payment year and future years. Additionally, we are proposing to adjust our currently approved burden estimates based on more recent data.

Specifically, we are proposing to revise § 414.1360(a)(2) to state that, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year. In section

IV.A.3.d.(3)(b) of this rule, we discussed stakeholder requests through the Quality Payment Program help desk to apply the 50 percent threshold to a portion of clinicians in a group. We anticipate that clinicians would find applicable and meaningful activities specific to practice size, specialty, or practice setting. Therefore, we assume that the proposal to apply the 50 percent minimum threshold to clinicians who submit for the improvement activity performance category as part of groups, virtual groups, or choose to participate as subgroups beginning with the CY 2023 MIPS performance period/2025 MIPS payment year would not present additional complexity or burden.

We do not believe the proposed changes to the improvement activities inventory will impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. Therefore, we are not proposing to revise the estimated time of 5 minutes (per response) currently approved for improvement activities submission.

As represented in Table 100, based on data from the CY 2019 MIPS performance period/2021 MIPS payment year, we estimate that a total of 81,562 respondents consisting of 63,845 individual clinicians and 17,717 groups will submit improvement activities during the 2022 MIPS performance period/2024 MIPS payment year. Since our currently approved burden sets out 79,927 respondents, this represents an increase of 1,635 respondents (81,562 respondents − 79,927 active respondents). This is an increase of 1,242 individuals and 393 groups from the estimates of 62,603 individuals and 17,324 groups provided in the CY 2021 PFS final rule due to availability of updated data (85 FR 50362).

As discussed in sections V.B.8.e. and V.B.8.g.(3) of this proposed rule regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we are proposing to update our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or participating in an ACO in the CY 2019 MIPS performance period/2021 MIPS payment year but will be QPs in the CY 2022 MIPS performance period/2024 MIPS payment year, and will therefore not be required to submit improvement activities data.

TABLE 100: Estimated Number of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians in CY 2022

	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2022 MIPS performance period (a)	63,845
# of Groups to submit improvement activities on behalf of clinicians during the CY 2022 MIPS performance period (b)	17,717
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2022 MIPS performance period (CY 2022 Proposed Rule) (c) = (a) + (b)	81,562
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2020 MIPS performance period (CY 2021 PFS Final Rule) (d)	79,927
Difference (e) = (c) - (d)	**+1,635**

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

As discussed in section IV.A.3.b.(2)(d)(ii) of this proposed rule, we are proposing subgroup reporting in the CY 2023 MIPS performance period/2025 MIPS payment year. As we discussed in section V.B.8.e.(7)(a) of this proposed rule, we estimate that there will be 20 subgroup reporters in the CY 2023 MIPS performance period/2025 MIPS payment year, each of which will have burden related to the submission of improvement activities. We have included this burden in Table 101.

TABLE 101: Estimated Number of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians in CY 2023

	Count
# of clinicians to participate in improvement activities data submission as individuals during the CY 2023 MIPS performance period (a)	63,845
# of Groups to submit improvement activities on behalf of clinicians during the CY 2023 MIPS performance period (b)	17,717
# of Subgroups to submit improvement activities in MVPs during the CY 2023 MIPS performance period (c)	20
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 MIPS performance period (CY 2022 PFS Proposed Rule) (d) = (a) + (b) + (c)	81,582
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2020 MIPS performance period (CY 2021 PFS Final Rule) (e)	79,927
Difference (f) = (d) - (e)	**+1,655**

Consistent with the CY 2021 PFS final rule, we continue to estimate that the per response time required per individual or group is 5 minutes for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (84 FR 63140).

As shown in Table 102, we estimate an annual burden of 6,797 hours (81,562 responses × 5 minutes/60) and $647,210 (6,797 hr × $95.22/hr)) in CY 2022 MIPS performance period/2024 MIPS payment year.

TABLE 102: Estimated Burden for Improvement Activities Submission in CY 2022

	Burden Estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2022 MIPS performance period (a)	81,562
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c) = (a) * (b)	**6,797**
Labor rate for a computer systems analyst to submit improvement activities (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$647,210**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 103, with the introduction of subgroup reporting in the CY 2023 MIPS performance period/2025 MIPS payment year, we estimate an annual burden of 6,799 hours (81,582 responses × 5 minutes/60) and $647,401 (6,799 hr × $95.22/hr)).

TABLE 103: Estimated Burden for Improvement Activities Submission in CY 2023

	Burden Estimate
Total # of Respondents (Groups, Subgroups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the CY 2023 MIPS performance period (a)	81,582
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c) = (a) * (b)	**6,799**
Labor rate for a computer systems analyst to submit improvement activities (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$647,401**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 104, using our unchanged currently approved per respondent burden estimate, the increase of 1,635 in the number of respondents results in an adjustment of 136 hours (1,635 responses × 5 minutes/60) at a cost of $12,973 (136 hr × $95.22/hr).

TABLE 104: Adjusted Burden for Improvement Activities Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	6,661
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 102, row (c))	6,797
Difference (c) = (b) - (a)	**+136**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$634,221
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 102, row (e))	$647,210
Difference (f) = (e) - (d)	**+$12,989**

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The proposed requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53922), CY 2019 PFS final rule (83 FR 60017 through 60018), CY 2020 PFS final rule (84 FR 63141) and the CY 2021 PFS final rule (85 FR 84989 through 85 FR 84990) for our previously finalized requirements and information collection burden for the nomination of improvement activities.

In section IV.A.3.d.(3)(c)(i)(B) of this rule, we are proposing: (1) To revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (2) changes to the timeline for improvement activities nomination during a public health emergency (PHE); and (3) to suspend activities that become obsolete or impacted by clinical practice guideline changes from the program when this occurrence happens outside of the rulemaking process.

In section IV.A.3.d.(3)(c)(i)(B)(cc) of this rule, we are proposing 2 new criteria that beginning with the CY 2022 Annual Call for Activities MIPS improvement activities: (1) Should not duplicate other improvement activities in the Inventory; and (2) should drive improvements that go beyond purely common clinical practices.

Additionally, we are proposing to increase the number of criteria stakeholders are required to meet when submitting an activity proposal from a minimum of 1 to all 8 criteria, which includes the two new proposed criteria. We believe that this proposal would provide clearer guidance to stakeholders when submitting a nomination for an improvement activity. In the CY 2021 PFS final rule, we estimated that it would require 0.6 hours for a medical and health services manager or equivalent and 0.4 hours for a physician to link the nominated improvement activity to existing and related cost and quality measures (85 FR 84989). Given that our current approved estimated time per respondent to nominate an improvement activity is 3 hours (1.8 hours for a medical and health services manager or equivalent and 1.2 hours for a physician), we assume that the proposed new requirement to meet all 8 criteria would require approximately 1 hour at $114.24/hr for a medical and health services manager to identify and submit an activity and 0.4 hours at a rate of $217.32/hr for a clinician to review each activity. Combined with our currently approved burden estimate, we propose to revise our estimate to 2.8 hours at $114.24/hr for a medical and health services manager or equivalent and 1.6 hours at $217.32/hr for a physician to nominate an improvement activity. This represents a change of +1 hours (2.8 hr − 1.8 hr) for a medical and health services manager or equivalent and +0.4 hours (2 hr − 1.6 hr) for a physician and an overall increase of 1.4 hours. We considered whether we should double our estimates for nomination of an improvement activity to 6 hours. Since only 2 of the required

8 criteria are new, we assume that stakeholders are familiar with the existing criteria and would not need additional time to review but would need the additional time to verify and confirm if the considered activity meets all the 8 criteria. We seek comment on our proposed estimate to revise the time for nomination of an improvement activity to 4.4 hours and if there are additional burden implications that we should consider for above proposals to revise the criteria.

In the CY 2021 PFS final rule, we finalized an exception stating that during public health emergencies (PHE) stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe (85 FR 84989). Instead of only accepting nominations and modifications submitted February 1st through July 1 each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). In section IV.A.3.d.(3)(c)(i)(B)(aa)of this rule, we are proposing to clarify that in order to implement a new improvement activity for a PHE during the same year as the nomination, the nomination would need to be received no later than January 5th of the nomination year to be included in a rule for notice-and-comment rulemaking during that fiscal or calendar year, a necessary precursor to implementation if it were to be finalized, as described above.

We believe this proposal will not affect our currently approved burden estimates since we assume that the number of nominations will not change, but it would make an activity available for reporting to clinicians in the same performance year it was intended to be implemented. Similar to our assumptions in the CY 2021 PFS final rule (85 FR 84989), we expect additional nominations may be received as a result of this change. However, we do not have any data with which to estimate what the additional number may be. As a result, we are not making any proposed revisions to our currently approved burden estimate.

In section IV.A.3.d.(3)(c)(i)(C)(aa) of this rule, we are proposing that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year we are proposing that for each improvement activity that is in the Inventory, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline, it will be removed from the program as soon as possible. In the CY 2020 PFS final rule (84 FR 62988 through 62990), we finalized the factors for consideration in removing improvement activities. Following the publication of the CY 2021 PFS proposed rule, the improvement activities team became aware that clinicians could no longer complete the activity from April 1 through December 31, 2020, because one of the improvement activities in the Inventory had expired on March 31, 2020. We do not anticipate any burden for stakeholders because of the above proposal as described, the proposed policy does not change requirements for the nomination of improvement activities. This proposal would help avoid stakeholder confusion and ensure the accuracy of the available activities in the Inventory. Therefore, we are not proposing to revise our estimated burden due to the above proposed policy.

Additionally, consistent with our assumptions in the CY 2021 PFS final rule (85 FR 84990) we continue to use our currently approved assumption that we will receive 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2023 Improvement Activities Inventory. The 2021 Annual Call for Activities ends on July 1, 2021; assuming updated information is available, we will update our estimate in the final rule.

As shown in Table 105, accounting for the change in burden per respondent estimate due to the provision to require all the 8 criteria for nomination of an improvement activity as described above in this section, we propose to revise our estimated annual information collection burden to 136 hours (31 nominations × 4.4 hr/nomination) at a cost of $20,695 (31 × [(2.8 hr × $114.24/hr) + (1.6 hr × $217.32/hr)]).

TABLE 105: Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
# of Nominations of New Improvement Activities (a)	31
# of Hours Per Medical and Health Services Manager to Identify and Nominate Activity (b)	2.8
# of Hours Per Physician to Identify Activity (c)	1.6
Annual Hours Per Respondent (d)= (b) + (c)	4.4
Total Annual Hours (e) = (a) * (d)	**136**
Cost to Identify and Submit Activity (@ medical and health services manager's labor rate of $114.24/hr) (f) = $114.24/hr * (b)	$319.87
Cost to Identify Improvement Activity (@ physician's labor rate of $210.44/hr) (g) = $217.32/hr * (c)	$347.71
Total Annual Cost Per Respondent (h)=(f)+(g)	$667.58
Total Annual Cost (i) = (a) * (h)	**$20,695**

As shown in Table 106, using our unchanged estimate of the number of activities nominated, the increase in the burden per nomination results in a change of 43 hours (31 nominations × 1.4 hr/nomination) at a cost of $6,492 (31 activities × [(1 hr × $114.24/hr) + (0.4 hr × $217.32/hr)]).

TABLE 106: Change in Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	93
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 105, row (e))	136
Difference (c) = (b) - (a)	**+43**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$14,203
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 105, row (i))	$20,695
Difference (f) = (e) - (d)	**+$6,492**

k. Nomination of MVPs

This rule does not propose any new or revised collection of information requirements or burden related to the nomination of MVPs for inclusion in the Quality Payment Program. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the proposed policies in this rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not proposing any changes under that control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule does not propose any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we are proposing to adjust our currently approved burden estimates based on updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year. The proposed adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 107, based on our predictive QP analysis for the 2022 QP performance period/2024 payment year, which accounts for historical response rates in the CY 2020 MIPS performance period/2022 MIPS payment year, we propose to revise our estimate that 150 APM Entities and 100 eligible clinicians (representing approximately 9,000 Partial QPs) will make the election to participate as a Partial QP in MIPS, a total of 250 elections which is a decrease of 50 from the 300 elections that are currently approved by OMB under the aforementioned control number. We continue to estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we propose to revise our estimated annual burden to 63 hours (250 respondents × 0.25 hr/election) and $5,999 (63 hr × $95.22/hr).

TABLE 107: Estimated Burden for Partial QP Election

	Burden Estimate
# of respondents making Partial QP election (100 APM Entities, 200 eligible clinicians) (a)	250
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a) * (b)	**63**
Labor rate for computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$5,999**

As shown in Table 108, using our unchanged currently approved per respondent burden estimate, the proposed decrease in the number of Partial QP elections results in an adjustment of 12.5 hours (−50 elections × 0.25 hr) at a cost of −$1,191 (−12.5 hr × $95.22/hr) (85 FR 84991).

TABLE 108: Adjusted Burden for Partial QP Election

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	75
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 107, row (c))	63
Difference (c) = (b)-(a)	**-12**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$7,142
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 107, row €)	$5,999
Difference (f) = –€ - (d)	**-$1,143**

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician Initiated Process (§ 414.1445)

The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements related to the Payer-Initiated Process. However, we are proposing to adjust our currently approved burden estimates based on updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year.

As shown in Table 109, based on the actual number of requests received in the 2020 QP performance period, we propose to revise our estimate that for the 2023 QP performance period, 15 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (6 Medicaid payers, 6 Medicare Advantage Organizations, and 3 remaining other payers), a decrease of 65 from the 80 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We propose to revise our estimated annual burden to 150 hours (15 submissions × 10 hr/submission) and $14,283 (150 hr × $95.22/hr).

TABLE 109: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
# of other payer payment arrangements (3 Medicaid, 3 Medicare Advantage Organizations, 1 remaining other payers) (a)	15
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	**150**
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$14,283**

As shown in Table 110, using our unchanged currently approved per respondent burden estimate, the proposed decrease in the number of payer-initiated requests from 800 to 150 results in an adjustment of −650 hours (−65 requests × 10 hr) at a cost of −$61,893 (−650 hr × $95.22/hr) (85 FR 84992).

TABLE 110: Adjusted Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	800
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 109, row (c))	150
Difference (c) = (b) - (a)	**-650**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$76,176
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 109, row (e))	$14,283
Difference (f) = (e) - (d)	**-$61,893**

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule does not propose any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. However, we are proposing to adjust our currently approved burden estimates based on updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year. As mentioned above, the new and adjusted burden will be submitted to OMB for approval.

As shown in Table 111, based on the actual number of requests received in the 2020 QP performance period, we estimate that in CY 2022 for the 2023 QP performance period, 15 Eligible-Clinician Initiated request for Other Payer Advanced APM determinations will be submitted, a decrease of 135 from the 150 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We propose to revise our estimated annual burden to 150 hours (15 submissions × 10 hr/submission) and $14,283 (150 hr × $95.22/hr).

TABLE 111: Estimated Burden for Other Payer Advanced APM Identification Determinations: Eligible Clinician Initiated Process

	Burden Estimate
# of other payer payment arrangements from APM Entities and eligible clinicians	15
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a) * (b)	**150**
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$14,283**

As shown in Table 112, using our unchanged currently approved per respondent burden estimate, the proposed decrease in the number of eligible clinician-initiated requests from 150 to 15 results in an adjustment of −1,350 hours (−135 requests × 10 hr) at a cost of −$128,547 (−1,350 hr × $95.22/hr) (85 FR 84993).

TABLE 112: Adjusted Burden for Other Payer Advanced APM Identification Determinations: Eligible Clinician Initiated Process

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	1,500
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 111, row (c))	150
Difference (c) = (b) - (a)	**-1,350**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	142,830
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 111, row (e))	14,283
Difference (f) = (e) - (d)	**-$128,547**

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule does not propose any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not proposing any changes under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule does not propose any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we are proposing adjustments to our currently approved burden estimates based on data from the CY 2019 MIPS performance period/2021 MIPS payment year. The proposed adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53924 through 53925), CY 2019 PFS final rule (83 FR 60022), CY 2020 PFS final rule (84 FR 63145 through 63146) and the CY 2021 PFS final rule (85 FR 84993) for our previously finalized requirements and burden for voluntary participants to opt-out of public reporting on Physician Compare.

In the CY 2021 PFS final rule (85 FR 84993), we estimated that 10 percent of the clinicians and groups who voluntarily participate in MIPS would opt out of public reporting. Based on the number of opt-out eligible clinicians that chose to opt-out of public reporting in the CY 2019 MIPS performance period/2021 MIPS payment year, we propose to revise our estimates. We anticipate that 0.1 percent of the total clinicians and groups who will voluntarily participate in the CY 2022 MIPS performance period/2024 MIPS payment year will also elect not to participate in public reporting. This results in a total of 38 (0.001 × 37,934 voluntary MIPS participants) clinicians and groups, a decrease of 3,448 from the currently approved estimate of 3,486. Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the RIA section of the CY 2019 PFS final rule, we continue to estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

Table 113 shows that for these voluntary participants, we continue to estimate it will take 0.25 hours for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 9.5 hours (38 requests × 0.25 hr/request) and $904 (9.5 hr × $95.22/hr).

TABLE 113: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	38
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a) * (b)	**9.50**
Labor rate for a computer systems analyst (d)	$95.22/hr
Total Annual Cost (e) = (c) * (d)	**$904**

As shown in Table 108, using our unchanged currently approved per respondent burden estimate, the decrease of 3,448 opt outs by voluntary participants results in an adjustment of −862 hours (−3,448 requests × 0.25 hr) at a cost of $−82,079 (−862 hr × $95.22/hr).

TABLE 114: Adjusted Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
Total Annual Hours for Respondents in CY 2021 PFS Final Rule (a)	871.5
Total Annual Hours for Respondents in CY 2022 PFS Proposed Rule (b) (see Table 113, row (c))	9.5
Difference (c) = (b)-(a)	**-862**
Total Annual Cost for Respondents in CY 2021 PFS Final Rule (d)	$82,984
Total Annual Cost for Respondents in CY 2022 PFS Proposed Rule (e) (see Table 113, row (e))	$904
Difference (f) = (e)-(d)	**-82,079**

p. Summary of Annual Quality Payment Program Burden Estimates

Table 115 summarizes this proposed rule's total burden estimates for the Quality Payment Program for both the CY 2022 and CY 2023 MIPS performance periods/2024 and 2025 MIPS payment years. In the CY 2021 PFS final rule, the total estimated burden for the CY 2022 MIPS performance period/2024 MIPS payment year was 1,473,741 hours at a cost of $144,034,968 (85 FR 84994). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2021 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2021 PFS final rule into the CY 2022 MIPS performance period/2024 MIPS payment year is 1,468,547 hours at a cost of $148,093,881. These represent a decrease of 5,194 hours and an increase of $4,058,913. To understand the burden implications of the proposed policies in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2021 PFS final rule into the CY 2022 MIPS performance periods/2024 MIPS payment year. This burden estimate of 1,424,726 hours at a cost of $143,682,174 reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, a decrease of 43,821 hours and $4,411,707. This burden estimate is lower than the burden approved for information collection related to the CY 2021 PFS final rule due to updated data and assumptions. Our total burden estimate for the CY 2022 MIPS performance period/2024 MIPS payment year is 1,428,537 hours and $144,040,730, which represents a decrease of 40,010 hours and $4,053,151 from the CY 2021 PFS final rule. The difference of +3,811 hours (43,821 hours − 40,010 hours) and +$358,556 ($4,385,824 − $4,026,590) between this estimate and the total burden shown in Table 115 is the reduction in burden associated with impacts of the policies proposed for the CY 2022 MIPS performance period/2024 MIPS payment year, which includes the re-introduction of the CMS Web Interface measures as a collection type/submission type.

Table 115 also offers a comparison between the total currently approved estimated burden from the CY 2021 PFS final rule and our proposed estimated burden for the CY 2023 MIPS performance period/2025 MIPS payment year. Our total burden estimate for the CY 2023 MIPS performance period/2025 MIPS payment year is 1,383,744 hours and $139,516,153, which represents a decrease of 84,803 hours and $8,577,728 from the CY 2021 PFS final rule. The difference of −40,982 hours (43,821 hours − 84,803 hours) and −$4,166,021 ($4,411,707 − $8,577,728) between this estimate and the total burden shown in Table 115 is the reduction in burden associated with impacts of the policies proposed for the CY 2023 MIPS performance period/2025 MIPS payment year. These policy changes include the proposals to sunset the CMS Web Interface measures as a collection type/submission type and to implement a new information collection for MVPs and subgroups.

We have included Table 115 to assist in understanding these differences. Note that the difference between the burden estimates for the CY 2022 and 2023 MIPS performance periods/2024 and 2025 MIPS payment years is entirely due to the proposed policies to introduce MVP and subgroup reporting and sunset the CMS Web Interface measures as a collection type/submission type beginning in the CY 2023 MIPS performance period/2025 MIPS payment year.

TABLE 115: Summary of Proposed Burden Estimates and Requirements from the CY 2022 PFS Proposed Rule

CY 2022 MIPS Performance Period		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2021 PFS Final Rule (a)	1,473,741	$144,034,968
CY 2022 PFS Proposed Rule w/ updated wage rates and ICRs (b)	1,468,547	$148,093,881
CY 2022 PFS Proposed Rule w/ updated data and assumptions (c)	1,424,726	$143,682,174
Change in burden due to updated data and assumptions (d) = (c) – (b)	-43,821	-$4,411,707
CY 2022 PFS Proposed Rule Total Burden (e)	1,428,537	$144,040,730
Total change in burden (f) = (e) – (b)	-40,010)	-$4,053,151
Change in burden associated with policies (g) = (f) – (d)	+3,811	+$358,556
CY 2023 MIPS Performance Period		
Burden Estimate Description	**Time (Hours)**	**Cost**
Currently approved burden in CY 2021 PFS Final Rule (h)	1,473,741	$144,034,968
CY 2022 PFS Proposed Rule w/ updated wage rates and ICRs (i)	1,468,547	$148,093,881
CY 2022 PFS Proposed Rule w/ updated data and assumptions (j)	1,424,726	$143,682,174
Change in burden due to updated data and assumptions (k) = (j) – (i)	-43,821)	-$4,411,707
CY 2022 PFS Proposed Rule Total Burden (l)	1,383,744	$139,516,153
Total change in burden (as shown in Table 118) (m) = (l) – (i)	-84,803	-$8,577,728
Change in burden associated with policies (n) = (m) – (k)	-40,982	-4,166,021

TABLE 116: Summary of Quality Payment Program Burden Estimates and Requirements for the CY 2022 MIPS Performance Period/ 2024 MIPS Payment Year CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses*	Proposed Responses	Change in Responses	Currently Approved Total Time (Hours)*	Proposed Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR self-nomination (see section V.B.8.c.(2)* (See Table 71)	82	90	+8	826	1,265	+439
§ 414.1400 Registry self-nomination (see section V.B.8.c.(3)* (See Table 73)	193	220	+27	1,139	1,137	-2
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section V.B.8.e.(4)): 2022 Performance Period (See Table 79)	29,273	28,252	-1,021	415,677	401,178	-14,499
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section V.B.8.e.(5)): 2022 Performance Period (See Table 82)	52,949	52,036	-913	480,936	472,643	-8,293
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section V.B.8.e.(6)): 2022 Performance Period (See Table 84)	50,470	48,573	-1,897	403,760	388,584	-15,176
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section V.B.8.e.(8)): 2022 Performance Period (See Table 88)	0	114	+114	0	7,030	+7,030
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section V.B.8.e.(10)): 2022 Performance Period (See Table 91)	0	90	+90	0	22.5	+22.5
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section V.B.8.g.(2)) (See Table 94)	52,099	42,827	-9,272	13,025	10,707	-2,318
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section V.B.8.g.(3)): 2022 performance period (See Table 99)	53,636	51,647	-1,989	143,029	138,930	-4,099
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section V.B.8.i): 2022 (See Table 104)	79,927	81,562	+1,635	6,661	6,797	+136
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section V.B.8.j) (See Table 106)	31	31	+0	93	136	+43
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section V.B.8.m) (See Table 108)	300	250	-50	75	63	-12
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process (see section V.B.8.n.(1)) (See Table 110)	80	15	-65	800	150	-650
§ 414.1445 Eligible Clinician Initiated Process (see section V.B.8.n.(2)) (See Table 112)	150	15	-135	1,500	150	-1,350
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section V.B.8.o) (See Table 114)	3,486	38	-3,448	872.00	10	-862
TOTAL	322,676	305,760	-16,916	1,468,393	1,428,803	-39,591

*Total Responses is equal to the number of self-nomination applications plus the number of Corrective Action Plans submitted.

TABLE 117: Summary of Quality Payment Program Burden Estimates and Requirements for the CY 2023 MIPS Performance Period/ 2025 MIPS Payment Year CMS-10621 (OMB 0938-1314)

Requirement	Currently Approved Responses*	Proposed Responses	Change in Responses	Currently Approved Total Time (Hours)*	Proposed Total Time (Hours)	Change in Total Time (Hours)
§ 414.1400 QCDR self-nomination (see section V.B.8.c.(2))* (See Table 71)	82	90	+8	826	1,265	+439
§ 414.1400 Registry self-nomination (see section V.B.8.c.(3))* (See Table 73)	193	220	+27	1,139	1,137	-2
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section V.B.8.e.(4)): 2023 Performance Period (See Table 80)	29,273	25,427	-3,846	415,677	361,061	-54,616
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section V.B.8.e.(5)): 2023 Performance Period (See Table 82)	52,949	46,877	-6,072	480,936	425,787	-55,149
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section V.B.8.e.(6)): 2023 Performance Period (See Table 84)	50,470	43,773	-6,697	403,760	350,186	-53,574
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section V.B.8.e.(8)): 2023 Performance Period (See Table 89)	0	0	0	0	0	0
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section V.B.8.e.(10)): 2023 Performance Period (See Table 91)	0	0	0	0	0	0
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section V.B.8.g.(2)) (See Table 94)	52,099	42,827	-9,272	13,025	10,707	-2,318
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section V.B.8.g.(3)): 2023 Performance Period (See Table 99)	53,636	51,667	-1,969	143,029	138,984	-4,045
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section V.B.8.i): 2023 Performance Period (See Table 104)	79,927	81,582	+1,655	6,661	6,799	+138
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section V.B.8.j) (See Table 106)	31	31	0	93	136	+43
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section V.B.8.m) (See Table 108)	300	250	-50	75	63	-12
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process (see section V.B.8.n.(1) (See Table 110)	80	15	-65	800	150	-650
§ 414.1445 Eligible Clinician Initiated Process (see section V.B.8.n.(2)) (See Table 112)	150	15	-135	1,500	150	-1,350
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section V.B.8.o) (See Table 114)	3,486	38	-3,448	872	10	-862
MVP Registration (see section V.B.8.e.(7)(a)(i)): 2023 Performance Period (See Table 85)	0	12,918	+12,918	0.00	3,230	+3,230
Subgroup Registration (see section	0	20	+20	0.00	10	+10

Requirement	Currently Approved Responses*	Proposed Responses	Change in Responses	Currently Approved Total Time (Hours)*	Proposed Total Time (Hours)	Change in Total Time (Hours)
V.B.8.e.(7)(a)(ii)): 2023 Performance Period (See Table 86)						
MVP Quality Submission (see section V.B.8.e.(7)(a)(iii)): 2023 Performance Period (See Table 87)	0	12,918	+12,918	0.00	83,673	+83,673
TOTAL	322,676	318,668	-4,008	1,468,393	1,383,348	-85,045

*Total Responses is equal to the number of self-nomination applications plus the number of Corrective Action Plans submitted.

The following table represents averages for the estimated changes in burden for the CY 2022 and CY 2023 MIPS performance periods/2024 and 2025 MIPS payment years.

TABLE 118: Calculating Average Total Change in Burden

Changes Under §§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
CY 2022 MIPS Performance Period	119,890	-3,729	Varies	-40,010	Varies	-$4,053,151
CY 2023 MIPS Performance Period	119,910	-3,709	Varies	-84,803	Varies	-$8,577,728
TOTAL	239,800	-7,438	Varies	-124,813	Varies	-12,630,880
AVERAGE	119,900	-3,719	Varies	-62,407	Varies	-6,315,440

Table 119 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this proposed rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 5 policies that reflect updated data and revised methods.

TABLE 119: Reasons for Change in Burden Compared to the Currently Approved CY 2021 Information Collection Burden

Quality Payment Program Table	Proposed Changes in burden due to CY 2022 Proposed Rule policies	Adjustments in burden from continued CY 2021 PFS Final Rule policies due to revised methods or updated data
Section V.B.8.c.(2): QCDR Self-Nomination and other Requirements (See Table 72)	Increase in burden due to the proposed policy requiring submission of participation plans, as necessary (3 hours per plan). Increase in burden due to current policies not previously having a burden estimate. (QCDR pre-existing measures)	Increase in number of hours required for simplified and full self-nomination process.
Section V.B.8.c.(3): Qualified Registry Self-Nomination and other Requirements (See Table 74)	Increase in burden due to the proposed policy requiring submission of participation plans, as necessary (3 hours per plan).	Decrease in the estimated number of hours required for full-self nomination process
Section V.B.8.e.(4): Quality Performance Category Medicare Part B Claims Collection Type (See Table 80)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Decrease in burden due to estimated 10% of submitters reporting through MVPs. This decrease is offset slightly by the addition of Web Interface submitters due to the sunset of the CMS Web Interface collection type.	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year and updated QP projections for the CY 2022 MIPS performance period/2024 MIPS payment year.
Section V.B.8.e.(5): Quality Performance Category QCDR/ MIPS CQM Collection Type (See Table 82)	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Decrease in the number of respondents due to the proposed policy to extend the CMS Web Interface measures as a collection type/submission type for the CY 2022 MIPS performance period/2024 MIPS payment year. (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Increase in the number of respondents due to the proposed policy to sunset the CMS Web Interface measures as a collection type/submission type and decrease in respondents due to proposed MVP implementation.	Decrease in number of respondents due to updated projections from the CY 2022 MIPS performance period/2024 MIPS payment year and updated QP projections for the CY 2022 MIPS performance period/2024 MIPS payment year.

Quality Payment Program Table	Proposed Changes in burden due to CY 2022 Proposed Rule policies	Adjustments in burden from continued CY 2021 PFS Final Rule policies due to revised methods or updated data
Section V.B.8.e.(6): Quality Performance Category eCQM Collection Type (See Table 84)	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Decrease in the number of respondents due to the proposed policy to extend the CMS Web Interface measures as a collection type/submission type for the CY 2022 MIPS performance period/2024 MIPS payment year. (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Increase in number of respondents due to the proposed policy to sunset the CMS Web Interface measures as a collection type/submission type and decrease in respondents due to proposed MVP implementation.	Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year and updated QP projections for the CY 2022 MIPS performance period/2024 MIPS payment year.
SSectionV.B.8.e.(7)(a)(i) : MVP Registration (See Table 85)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) New information collection request	Not applicable
Section V.B.8.e.(7)(a)(ii) : Subgroup Registration (See Table 86)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) New information collection request	Not applicable
Section V.B.8.e.(7)(a)(iii) : MVP Quality Performance Category Submission (See Table 87)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) New information collection request	Not applicable
Section V.B.8.e.(8): Quality Performance Category CMS Web Interface Collection Type (See Table 89)	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Addition of information collection due to the proposed policy to extend the CMS Web Interface measures as a collection type/submission type. (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Removal of information collection due to the proposed policy to sunset the CMS Web Interface measures as a collection type/submission type.	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Increase in number of respondents (+114) due to proposed policy to extend the CMS Web Interface measures as a collection type/submission type. (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Decrease in number of respondents (-114) due to proposed policy to sunset the CMS Web Interface measures as a collection type/submission type.
Section V.B.8.e.(10): Registration for CMS Web Interface (See Table 91)	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Addition of information collection due to the proposed policy to extend the CMS Web Interface measures as a collection type/submission type. (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Removal of information collection due to the proposed policy to sunset the CMS Web Interface measures as a collection type/submission type.	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Increase in number of respondents (+90) due to proposed policy to extend the CMS Web Interface measures as a collection type/submission type. (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Decrease in number of respondents (-90) due to proposed policy to sunset the CMS Web Interface measures as a collection type/submission type.

Quality Payment Program Table	Proposed Changes in burden due to CY 2022 Proposed Rule policies	Adjustments in burden from continued CY 2021 PFS Final Rule policies due to revised methods or updated data
Section V.B.8.g.(2): Reweighting Applications for Promoting Interoperability and Other Performance Categories (See Table 94)	Decrease in the number of respondents due to the proposed policy to allow automatic reweighting of the Promoting Interoperability performance category for small practices	None
Section V.B.8.g.(3): Promoting Interoperability Performance Category Data Submission (See Table 99)	(CY 2022 MIPS Performance Period/2024 MIPS Payment Year) Increase in per response burden (+0.02 hours) due to the proposed policy for annual assessment SAFER Guides requirement (CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Increase in number of respondents (+20) due to the proposed implementation of subgroup reporting for MVPs and APP.	Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year and updated QP projections for the CY 2022 MIPS performance period/2024 MIPS payment year.
Section V.B.8.i: Improvement Activities Submission (See Table 104)	(CY 2023 MIPS Performance Period/2025 MIPS Payment Year) Increase in number of respondents (+20) due to the proposed implementation of subgroup reporting for MVPs and APP.	Increase in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year
Section V.B.8.j: Nomination of Improvement Activities (See Table 106)	Increase in per response burden (+1.4 hours) due to the proposed revised criteria for nomination of improvement activities	None.
Section V.B.8.m: Partial QP Election (See Table 108)	None	Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year.
Section V.B.8.n.(1): Other Payer Advanced APM Identification: Other Payer Initiated Process (See Table 110)	None.	Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year.
Section V.B.8.o: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare (See Table 114)	None.	Decrease in number of respondents due to updated projections for the CY 2022 MIPS performance period/2024 MIPS payment year.

C. Summary of Annual Burden Estimates for Proposed Changes

TABLE 120: Proposed Annual Requirements and Burden Estimates

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.806 (Requiring Certain Manufacturers to Report Drug Pricing Information for Part B)*	0938-0921	740	2,960	13	38,480	38.86	1,495,333
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan)*	0938-1396	100	100	0.1667	16.67	210.44	3,508
Part 403 (Open Payments Proposals included in the CY 2022 PFS)	0938-1237	2,398	2,398	Varies	1,263	Varies	64,561
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)**	0938-1314	119,900	-3,719	Varies	-62,407	Varies	-6,315,440
TOTAL		123,138	1,739	varies	-22,647.33	varies	-$4,752,038

*The finalized requirements and burden will be submitted to OMB using the standard PRA process.
**Averages the CY 2022 and CY 2023 MIPS performance period burden changes over the 2-year 2024 and 2025 MIPS payment years.

D. Submission of Comments

We have submitted a copy of this rule to OMB for its review of the rule's proposed information collection requirements and burden. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at *https://www.cms.gov/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html*, or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on the proposed information collection requirements and burden. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1751–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing to make payment and policy changes under the Medicare PFS and required statutory changes under the Consolidated Appropriations Act, 2016 and sections 2003 and 2005 of the SUPPORT for Patients and Communities Act of 2018. We are also proposing changes to payment policy and other related policies for Medicare Part B. In addition, if finalized, this proposed rule would make modest revisions to certain Medicare provider and supplier enrollment regulatory provisions and add already existing provider and supplier requirements pertaining to prepayment and post-payment review activities.

This proposed rule is necessary to make policy changes under Medicare fee-for-service and to address various provider and supplier enrollment issues. Therefore, we include a detailed Regulatory Impact Analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explain the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this proposed

rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This proposed rule will impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this proposed rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this proposed rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this proposed rule. The relevant sections of this proposed rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2021 with payment rates for CY 2022 using CY 2020 Medicare utilization. The payment impacts described in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2022, as required by section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments. In addition, section 101 of Division N of the CAA provided a 3.75 percent increase in PFS payment amounts for services furnished on or after January 1, 2021, and before January 1, 2022 and required that the increase shall not be taken into account in determining PFS payment rates for subsequent years. The expiration of this 3.75 percent increase in payment amounts will result in the CY 2022 conversion factor being calculated as though the 3.75 percent increase for the CY 2021 conversion factor had never been applied.

To calculate the CY 2022 PFS conversion factor (CF), we took the CY 2021 conversion factor without the 1-year 3.75 percent increase provided by the CAA and multiplied it by the budget neutrality adjustment required as described in the preceding paragraphs. We estimate the CY 2022 PFS CF to be 33.5848 which reflects the budget

neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.75 percent increase for services furnished in CY 2021, as provided in the CAA. We estimate the CY 2022 anesthesia CF to be 21.0442 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 121: Calculation of the CY 2022 PFS Conversion Factor

CY 2021 Conversion Factor		34.8931
Conversion Factor without CY 2021 Consolidated Appropriations Act Provision		33.6319
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2022 Conversion Factor		**33.5848**

TABLE 122: Calculation of the CY 2022 Anesthesia Conversion Factor

CY 2021 National Average Anesthesia Conversion Factor		21.5600
Conversion Factor without CY 2021 Consolidated Appropriations Act Provision		20.7807
Statutory Update Factor	0.00 percent (1.0000)	
CY 2022 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2022 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	1.41 percent (1.0141)	
CY 2022 Conversion Factor		**21.0442**

Table 123 shows the payment impact of the policies contained in this proposed rule on PFS services, should CMS finalize this rule as proposed. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 123 (CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 123.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2020 utilization and CY 2021 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2022 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2022 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2022 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2022 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 123: CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$220	0%	-2%	0%	-2%
Anesthesiology	$2,755	0%	1%	0%	1%
Audiologist	$58	0%	-1%	0%	-1%
Cardiac Surgery	$203	0%	-1%	0%	-1%
Cardiology	$6,119	0%	-1%	0%	-2%
Chiropractic	$617	0%	0%	0%	0%
Clinical Psychologist	$814	0%	0%	0%	0%
Clinical Social Worker	$873	0%	0%	0%	0%
Colon And Rectal Surgery	$144	0%	0%	0%	0%
Critical Care	$367	0%	0%	0%	0%
Dermatology	$3,454	0%	-1%	0%	0%
Diagnostic Testing Facility	$682	0%	0%	0%	0%
Emergency Medicine	$2,525	0%	0%	0%	0%
Endocrinology	$506	0%	2%	0%	2%
Family Practice	$5,725	0%	2%	0%	2%
Gastroenterology	$1,476	0%	0%	0%	0%
General Practice	$368	0%	1%	0%	2%
General Surgery	$1,738	0%	0%	0%	0%
Geriatrics	$175	0%	1%	0%	2%
Hand Surgery	$222	0%	2%	0%	2%
Hematology/Oncology	$1,737	0%	-2%	0%	-2%
Independent Laboratory	$552	0%	-2%	0%	-2%
Infectious Disease	$639	0%	-1%	0%	-1%
Internal Medicine	$9,906	0%	1%	0%	1%
Interventional Pain Mgmt	$900	0%	1%	0%	1%
Interventional Radiology	$480	0%	-9%	0%	-9%
Multispecialty Clinic/Other Phys	$138	0%	0%	0%	0%
Nephrology	$2,303	0%	0%	0%	0%
Neurology	$1,354	0%	0%	0%	1%
Neurosurgery	$708	0%	0%	0%	0%
Nuclear Medicine	$50	0%	-2%	0%	-2%
Nurse Ancs / Ancs Asst	$2,092	0%	1%	0%	1%
Nurse Practitioner	$5,288	0%	1%	0%	1%
Obstetrics/Gynecology	$558	0%	1%	0%	1%
Ophthalmology	$4,365	0%	0%	0%	0%
Optometry	$1,108	0%	0%	0%	1%
Oral/Maxillofacial Surgery	$70	0%	-4%	0%	-4%
Orthopedic Surgery	$3,273	0%	1%	0%	1%
Other	$52	0%	-1%	0%	-1%
Otolarngology	$1,037	0%	-1%	0%	-1%
Pathology	$1,061	0%	-1%	0%	-1%
Pediatrics	$55	0%	1%	0%	1%
Physical Medicine	$1,030	0%	0%	0%	0%
Physical/Occupational Therapy	$3,976	-1%	-1%	0%	-2%
Physician Assistant	$2,810	0%	1%	0%	1%
Plastic Surgery	$319	0%	1%	0%	1%
Podiatry	$1,847	0%	1%	0%	1%
Portable X-Ray Supplier	$84	0%	10%	0%	10%
Psychiatry	$1,040	0%	1%	0%	1%
Pulmonary Disease	$1,471	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,660	0%	-5%	0%	-5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Radiology	$4,397	0%	-2%	0%	-2%
Rheumatology	$541	0%	-1%	0%	-1%
Thoracic Surgery	$302	0%	-1%	0%	-1%
Urology	$1,677	0%	0%	0%	0%
Vascular Surgery	$1,144	0%	-8%	0%	-8%
Total	$89,065	0%	0%	0%	0%

* Column F may not equal the sum of columns C, D, and E due to rounding.

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2. CY 2021 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including portable x-ray, family practice, hand surgery, general practice, and endocrinology, reflect increases relative to other physician specialties. These increases can be attributed largely to the proposed update to clinical labor pricing as the services that these specialties furnish rely primarily on clinical labor for their PE costs. These increases are also due to proposed increases in value for particular services in response to the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC), and CMS review and increased payments resulting from updates to supply and equipment pricing.

The estimated impacts for several specialties, including interventional radiology, vascular surgery, radiation oncology, and oral/maxillofacial surgery reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of the proposed clinical labor pricing update. The services furnished by these specialties involve PE costs that rely primarily on supply or equipment items and therefore are affected negatively by the proposed updates to clinical labor pricing. Since PE is budget neutralized within itself, increased pricing for clinical labor holds a corresponding relative decrease for other components of PE such as supplies and equipment. These decreases are also due to the proposed revaluation of individual procedures based on reviews by the AMA RUC and CMS, as well as decreases resulting from the continued phase-in implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreases due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 2 percent decrease for CY 2021 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 123), including comments received in response to the proposed valuations. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentage changes in Table 123 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty. To illustrate how impacts can vary within specialties, we created a public use file that models the expected percentage change in total RVUs per practitioner. Using CY 2020 utilization data, Total RVUs change between -1 percent and 1 percent for more than 52 percent of practitioners, representing more than 48 percent of the changes in Total RVUs for all practitioners, with variation by specialty. Some specialties, such as chiropractic, clinical social worker, and emergency medicine, exhibit little variation in changes in total RVUs per practitioner. For these specialties, more than 90 percent of these practitioners would experience a change in Total RVUs between -1 percent and 1 percent. Other specialties exhibit more variation in changes in total RVUs per practitioner. For example, for diagnostic testing facilities, 32 percent of IDTFs would experience a 5 percent or more decrease in Total RVUs, but these suppliers represent only 28 percent of Total RVUs for this specialty. Meanwhile, one percent of IDTFs would experience 10 percent or more increases in Total RVUs and these suppliers account for 28 percent of Total RVUs for this specialty.

b. Impact

Column F of Table 123 displays the estimated CY 2022 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2022 PFS proposed rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

D. Effect of Proposed Changes Related to Telehealth Services

Before the PHE for COVID–19, approximately 15,000 fee-for-service Medicare beneficiaries received a Medicare telemedicine service each

week. According to a report prepared by the Assistant Secretary for Planning and Evaluation (ASPE),[251] in the last week of April 2020, nearly 1.7 million beneficiaries received telehealth services. By April 2020, nearly half of all Medicare primary care visits were telehealth encounters, a level consistent with health care encounters more broadly. There are approximately 270 services currently included on the list of Medicare telehealth services, including more than 160 that were added on a temporary basis during the PHE for COVID–19 (including service categories such as emergency department visits, initial inpatient and nursing facility visits, and discharge day management services) that are covered through the end of the PHE. Preliminary data show that between mid-March and mid-October 2020, over 24.5 million out of 63 million Medicare beneficiaries and enrollees have received a Medicare telemedicine service during the PHE. It is important to note that preliminary data reflect that the largest increases in services furnished via telehealth communications systems, by beneficiary access/volume, were for services that were already on the Medicare telehealth services list before the PHE.

As discussed in section II.D. of this proposed rule, we are proposing to amend the regulatory definition of interactive telecommunications system for purposes of Medicare telehealth services to include audio-only communication technology under certain circumstances for mental health services furnished to established patients in their homes. We anticipate that this policy will increase utilization of Medicare telehealth mental health services relative to utilization that would occur without the change. The estimated cost impact on overall Medicare services is unclear, though these changes would largely maintain current policies and access to the specific mental health services that are available to beneficiaries during the PHE. By requiring that a modifier be appended to the claim to identify that the service was furnished via audio-only communication technology, we will be able to closely monitor utilization and address any potential concerns regarding overutilization through future rulemaking.

Section 123 of the CAA removed the geographic and site of service restrictions for telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, and requires that a physician or practitioner furnish an in-person, non-telehealth service to a beneficiary within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary, and thereafter, at intervals as specified by the Secretary. Section 125 of the CAA created a new Medicare provider type—the rural emergency hospital, effective beginning in CY 2023—and added rural emergency hospitals to the list of eligible telehealth originating sites at section 1834(m)(4)(C)(ii) of the Act. As discussed in section II.D. of this proposed rule, we are proposing to require that, as a condition of payment for a telehealth service described in section 1834(m)(7) of the Act, the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of service of a telehealth service as specified in section 1834(m)(7)(B)(i) of the Act.

We are also seeking comment on whether the required in-person, non-telehealth service could also be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. Given that the removal of the geographic and site of service restrictions for telehealth will expand the availability of mental health services, we anticipate that utilization of these mental health services will be comparable to observed utilization for mental health services during the COVID–19 PHE.

With regard to our proposal to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of CY 2023, we believe our proposals would provide clarity to the stakeholder community but will have a negligible impact on PFS expenditures. For example, services that have already been added to the permanent telehealth services list are furnished via telehealth, on average, less than 0.1 percent of the time they are reported. The statutory payment requirements for Medicare telehealth services under section 1834(m) of the Act, such as the originating site requirements related to geographic location and site of service, have limited increases in utilization outside of the COVID–19 PHE; however, we believe there is value in allowing physicians to furnish services added to the Medicare telehealth services list on a category 3 basis, and for patients to receive broader access to this care through telehealth. Additionally, for services added to the Medicare telehealth list on a Category 3 basis, outside of the circumstances of the PHE for COVID–19, all of the statutory restrictions under section 1834(m) of the Act will also apply to these services; therefore, we do not anticipate any significant increase in utilization.

E. Effect of Changes Related to Services Furnished in Whole or in Part by PTAs and OTAs

As discussed in section II.H., we are proposing revisions to the current de minimis policy for services furnished in whole or in part by PTAs/OTAs that we finalized in CY 2020 PFS final rule (84 FR 62702 through 62708) under which the CQ or CO modifier would apply when the PTA or OTA furnished more than 10 percent of a service or a 15-minute unit of service. Beginning January 1, 2022, CMS will apply a 15 percent reduction to the payment amount for a physical or occupational therapy service when the CQ/CO modifier is applied to the service. Our proposed revision to the policy would allow the PT/OT to bill without the CQ/CO modifier for the final 15-minute unit (in a multi-unit billing scenario) when the PT/OT meets the billing threshold of 8 minutes, which is when the minutes are greater than the midpoint (7.5 minutes) of the 15-minute unit, regardless of any minutes provided by the PTA/OTA for that final unit.

Under our proposal, the PT/OT services would not be inadvertently discounted as the result of any ''left-over'' minutes provided by the PTA/OTA when the therapist provides enough minutes on his or her own to meet the billing threshold amount. In these scenarios, the PTA's/OTA's minutes are considered immaterial for the purposes of billing. For example, if the PT/OT provided 23 minutes of a 15-minute service and the PTA/OTA provided another 20 minutes of the same service—three units of service can be billed for the 43 total minutes (38 minutes through 52 minutes). Here, one full 15-minute unit of service is billed without the CQ/CO modifier for the PT/OT service with 8 minutes remaining, and one full unit of service is billed with the CQ/CO modifier for the PTA/OTA service with 5 minutes remaining. Under the proposed policy, the third unit is billed without the CQ/CO modifier because the 8 minutes provided by the PT/OT meets the billing threshold amount. However, under our current de minimis policy, the 5 minutes provided by the PTA/OTA is more than 10 percent (it is 38 percent of the total service—PTA/OTA minutes divided by the total of PTA/OTA + PT/OT minutes: 5 divided by 13 = 38

[251] Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the Covid-19 Pandemic (*hhs.gov*).

percent) meaning the CQ/CO modifier is applied to the third and final unit of service.

Under our current *de minimis* policy, under which the CQ/CO modifier is applied whenever the PTA/OTA provides more than 10 percent of a service whether or not the PT/OT furnishes enough of the service to bill for it without the portion furnished by the PTA/OTA, stakeholders have expressed concern that the PT/OT has a financial incentive not to have the PTA/OTA provide any additional minutes, regardless of the individual patient's needs, when those minutes of service would lead to a reduced payment for a unit of a service. There may be a cost implication to our proposal as fewer billing scenarios may result in application of the CQ/CO modifiers and consequent payment reduction. However, we believe that basing our proposed policy on a ''midpoint rule'' in which the PT/OT provides enough minutes on their own (8 or more minutes) to bill for the final unit of a billing scenario could eliminate the PT's/OT's financial incentive to not provide appropriate therapy to an individual patient when it is furnished by the PTA/OTA. On the other hand, if we were to continue with our de minimis standard to apply to all billing scenarios for PTA/OTA services that exceed the 10 percent standard, we are uncertain how to gauge the overall costs of this policy because of the possible altered PT/OT behavioral change that is due to the financial incentives built into that policy as discussed above.

F. Other Provisions of the Regulation

1. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.A. of this proposed rule, we make multiple proposals related to RHCs and FQHCs. In terms of estimated impacts to the Medicare program, Payment for Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients as required by section 132 of the CAA, 2021 and Concurrent Billing for CCM and Transitional Care Management TCM Services for RHCs and FQHCs will have negligible impact to Medicare spending.

Section 130 requires that all independent RHCs are now subject to the per-visit limit (which is also referred to as ''cap'') and phases in an increase in the statutory payment cap over an 8-year period. The cap in CY 2021, for services furnished after March 31, is set at $100 per visit, then at $126 per visit in 2022; at $139 per visit in 2023; at $152 per visit in 2024; at $152 per visit in 2025; at $165 per visit in 2026; at $178 per visit in 2027; and at $190 per visit in 2028. Beyond 2028 the limit is updated by the applicable Medicare Economic Index (MEI).

This provision also controls the annual rate of growth in payments to certain provider-based RHCs whose payments are currently higher than the payment limit. Each year, but for services provided after March 31 in 2021, the payment limit shall be set at the greater of: (1) The RHC per visit amount from the prior year, increased by the percentage increase in the applicable MEI; and (2) the cap limits applicable to each year as described above. In order to be eligible for this ''grandfathering'' policy, the RHC must have been based in a hospital with fewer than 50 beds and enrolled in Medicare as of December 31, 2019.

Section 2 of H.R. 1868, enacted on April 14, 2021, made technical corrections to section 130. First, for an RHC that is hospital-based and whose parent hospital has fewer than 50 beds, the date by which the RHC must be Medicare-certified, in order to be grandfathered, is changed from December 31, 2019 to December 31, 2020. Next, a clinic that is owned by a hospital with fewer than 50 beds and that submitted certain applications (received by Medicare) for certification as a Medicare RHC prior to the end of 2020 is to be grandfathered, and its clinic-specific cap is to be set based on its 2021 cost per visit. Lastly, a grandfathered RHC must continue to be owned by a hospital with fewer than 50 beds; if the parent hospital exceeds 50 beds, the RHC will lose its grandfathered status.

Table 124 are the FY estimates (in millions) for the impact of section 130, which improves payments to RHCs. These providers are currently paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services, and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit. The RHC payment limit per visit for calendar year (CY) 2021 is $87.52, which is 1.4 percent higher than the CY 2020 payment limit of $86.31.

TABLE 124: Fiscal Year Estimates for the Impact of Section 130 of the CAA

Medicare (Part B)	2021	2022	2023	2024	2025	2026	2026	2028	2029	2030	2031	2022-26	2022-31
Part B benefits	10	180	160	230	310	390	490	580	640	700	750	1,270	4,430
Premium offset	–	-40	-40	-60	-80	-100	-120	-140	-160	-170	-190	-320	-1,100
Net Part B	10	140	120	170	230	290	370	440	480	530	560	950	3,330

In section III.B. of this proposed rule, we discuss that we are proposing to revise the regulatory requirement that an RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between an RHC or FQHC patient and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time telecommunications technology, but only when furnishing services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.

According to our analysis of Medicare Part B claims data for services furnished via Medicare telehealth under the PFS during the PHE, use of telehealth for many professional services spiked in utilization around April 2020 and diminished over time, but not to pre-pandemic levels. In contrast, Medicare claims data suggests that for mental health services both permanently and temporarily added to the Medicare Telehealth list, subsequent to April 2020, the trend is toward maintaining a steady state of usage over time. Given the expanded availability of mental health services at RHCs and FQHCs, we do anticipate that this policy will increase spending, however, we are not certain of the magnitude of this increase, since it is not clear at this time how or whether trends related to utilization of communication technology during the PHE will continue after such a time that the PHE were to end. While the estimated cost impact of this proposal is unclear, the proposed requirement that a modifier be appended to the claim to identify that the service was furnished via audio-only communication technology would allow us to closely monitor utilization and address any potential concerns

regarding overutilization through future rulemaking.

2. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802 and 414.806)

This provision implements new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of the CAA (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 401''). These new requirements will improve the accuracy of reported payment limits and limit the use of WAC-based pricing.

As described in section III.D.1. of this proposed rule, in considering whether to exclude repackagers from the reporting requirements at section 1847A(f)(2) of the Act, we conducted two analyses to estimate: (1) The proportion of repackaged products in our existing ASP data; (2) the number of new ASP submissions we can expect as a result of the new reporting requirements under section 401; and (3) the proportion of those (new) submissions that involve repackaged products.

Additionally, while we believe it will impact reporting volume and payment limits under section 1847A of the Act for many billing and payment codes, we are unable to estimate the magnitude of these effects for the following reasons. We estimate: (1) 361 non-reporting manufacturers (of either single source or multiple source drugs) will now be required to report ASP data under section 1847A(f)(2) of the Act; and (2) 6114 products payable under Part B that these non-reporting manufacturers sell. However, we do not know which Healthcare Common Procedure Coding System (HCPCS) code payment limits will be impacted by these 6114 products, nor do we know the sales volume of these 6114 products. Because this information is used to calculate volume-weighted ASP payment limits, we, are unable to quantitatively estimate the economic impacts of this provision (that is, the likely costs or savings) on beneficiaries, the government, and other stakeholders. (We note that the economic impacts on manufacturers, as a result of the information collection requirements of this provision is discussed in section V. of this proposed rule.)

For single source drugs, these changes may result in lower payment limits because, typically, the WAC plus 3 percent is higher than ASP plus 6 percent. This then translates to cost savings for both the government and beneficiaries, who will pay coinsurance on a lesser amount. However, for the reason stated previously, we are unable to predict the magnitude of this effect.

Similarly, payment limits for multiple source drugs could increase or decrease, and we are unable to predict the direction or magnitude of specific or aggregate effects at this time.

We do not anticipate that this provision of this proposed rule would necessitate the revision of existing Medicaid Drug Rebate Agreements.

We welcome comment on (1) the likely costs or savings to beneficiaries, the government, and other stakeholders and (2) other related impacts of this provision.

3. Determination of ASP for Certain Self-Administered Drug Products

a. Anticipated Effects

This provision implements new statutory requirements under section 1847A(g) of the Act, as amended by section 405 of the CAA 2021, (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 405''). As identified by the OIG studies discussed in section III.D.2. of this proposed rule, the CMS payment-limit determination under section 1847A of the Act includes all versions of a product marketed under a single FDA approval, and consistent with section 1847A(b)(5) of the Act, the payment-limit determination does not exclude products based on packaging. Thus, the volume-weighted, average-ASP determination can include self-administered versions that may lead to increased program and beneficiary costs because of distorted ASP-based payment limits. In particular, the OIG studies identified two billing and payment codes that included self-administered NDCs. The OIG study determined that as a result of the inclusion of these NDCs in the calculation of the ASP payment limit, Medicare payment amounts remained inflated in 2017 and 2018, causing the program and its beneficiaries to pay an additional $497 million during this period. Since 2014, current payment methodology has resulted in an additional $173 million in Medicare beneficiary coinsurance for these two NDCs. (See OIG's July 2020 report titled, ''Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars,'' available at *https://oig.hhs.gov/oei/reports/OEI-BL-20-00100.asp*.)

Implementation of the proposed regulatory changes has the potential to result in decreased payment limits for identified billing and payment codes that could, in turn, substantially reduce Medicare and beneficiary expenditures, as described in the OIG study. Since section 1847A(g)(3) of the Act requires CMS to implement the required payment changes beginning on July 1, 2021, these potential savings may be observed within the year.

By adding sections 1847A(g)(1) and (2) of the Act, section 405 also directs the OIG to conduct future studies with same or similar methodologies to those in the July 2020 report and directs CMS to apply the lesser of payment methodology to the applicable billing and payment codes. This has the potential to result in additional savings to the program and beneficiaries if additional products are identified by these periodic OIG studies.

b. Expected Benefits

Codifying the provisions set forth by section 405 would permit to CMS to apply the lesser of payment methodology at section 1847(g)(2) of the Act to billing and payment codes identified by future OIG studies (described in section III.D.2. of this proposed rule). This provision addresses distorted payment limits for these products and may result in payment amounts that are better aligned with versions of these products that are payable under Part B (for example, versions that are usually not self-administered). Although we are unable to quantify the total magnitude of the potential savings, these changes have the potential to substantially reduce program expenditures and beneficiary coinsurance.

4. Appropriate Use Criteria

Section 1834(q)(2) of the Act, as added by section 218(b) of the Protecting Access to Medicare Act (PAMA), established a program to promote the use of appropriate use criteria (AUC) for applicable imaging services furnished in an applicable setting.

In the CY 2019 PFS final rule (83 FR 59452), we performed a comprehensive regulatory impact analysis for this program. In this proposed rule, we are proposing to begin the payment penalty phase of the program on the later of January 1, 2023 or the January 1 of the year after the year in which the PHE for COVID–19 ends. Because, under our proposals, the payment penalty phase will be further delayed, we are updating the estimates for incremental changes from the regulatory impact analysis from the CY 2019 PFS final rule. Since we are not proposing new policy requirements nor do we have sufficient reason to change any of the assumptions made in the RIA finalized in the CY 2019 PFS (83 FR 60034 through 60044)

we are only updating the analysis to reflect 2019 Medicare claims data (updated from 2014). We identify four incremental changes from the CY 2019 PFS final rule estimates due to updated claims data: (1) Impact of required AUC consultations by ordering professionals; (2) impact to Medicare beneficiaries; (3) process efficiencies to potentially offset the estimated burden on Medicare beneficiaries; and (4) impact on transmitting orders for advanced diagnostic imaging services. Each of these incremental changes results in a lower estimate.

a. Impact of Required AUC Consultations by Ordering Professionals

As discussed in detail in the CY 2019 PFS final rule (83 FR 60035 through 60037), the annual impact estimate of consultations by ordering professionals was $70,001,700. In our estimates, we calculated the burden for auxiliary personnel to consult AUC under the direction of an ordering professional and the burden for ordering professionals to perform the consultation directly. We estimated that 90 percent of consultations would be performed by a medical assistant (occupation code 31–9092) and 10 percent of consultations would be performed by a general practitioner (occupation code 29–1062). We estimated that 43,181,818 2-minute consultations occur annually.

Using 2019 Medicare claims data as our basis for the analysis, we propose to change the methodology used to determine the volume of consultations and propose to use more granular data that will reduce potential double-counting of advanced diagnostic imaging services. For example, an imaging service furnished in an outpatient hospital department could have two claims associated with that service. There could be a claim from the facility and a claim from the physician that interprets that imaging service. In the CY 2019 RIA (83 FR 60034 through 60044) we were concerned that the estimate of 43,181,818 consultations may be an overestimate because it took into account total claims. For this CY 2022 RIA, we propose to change the method of counting the total number of advanced diagnostic imaging services that would be furnished under the AUC program which will correspond to the total number of consultations.

Using the Integrated Data Repository we identified Medicare claims using the following parameters: (1) 2019 Date of service; (2) claim lines containing one of the procedure codes identified in CR10481 and CR11268 at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R2040OTN.pdf* and *https://www.cms.gov/files/document/r2404otn.pdf*, respectively; and (3) claims types of outpatient or practitioner. Claims were then separated based on the setting in which the imaging service was furnished and further by claim type. Using only services billed on the professional claim type, the total number of claim lines containing one of the identified procedure codes was included to total 30,359,901 advanced diagnostic imaging services estimated to be subject to the AUC program. By using this combination, we believe we can reduce the risk of double-counting services to obtain a more accurate estimate of total number of diagnostic imaging services subject to the AUC program. Therefore, this analysis will use the estimate of 30,359,901 AUC consultations.

Using the May 2020 BLS mean hourly wages, we update our estimates for a medical assistant (occupation code 31–9092) with mean hourly wage of $17.75 and 100 percent fringe benefits for 90 percent of consultations (910,797 hours) to be $30,511,701 (910,797 hours × $33.50/hour). The occupation for general practitioner is no longer listed on the BLS so, instead, we update our estimate using the occupation code for general internal medicine physician (29–1216) with mean hourly wage of $101.42 and 100 percent fringe benefits for 10 percent of consultations (101,200 hours) to be $20,527,408 (101,200 hours × $202.84/hour). The updated total annual estimated impact of consultations is $51,039,109, for an incremental change (reduction) of $18,962,591.

b. Impact to Medicare Beneficiaries

In the CY 2019 PFS final rule, we estimated that the additional 2-minute consultation would impact the Medicare beneficiary when their advanced diagnostic imaging service is ordered by the ordering professional by introducing additional time to their office visit. For this update, we used the updated number of consultations calculated above from claims data, as well as the May 2020 BLS mean hourly wage. To estimate this annual cost, we multiplied the annual burden of 1,011,997 hours by the BLS occupation code that represents all occupations in the BLS (00–0000) as mean hourly wage plus 100 percent fringe ($54.14/hr) for a total estimate of $54,789,518 per year for an incremental change (reduction) of $13,211, 482. We also estimated that, over time, process efficiencies may be implemented. We assumed that 50 percent of practices implemented an improvement process that streamlined AUC consultation so Medicare beneficiaries spent the same amount of time in the physician's office regardless of whether an advanced diagnostic imaging service was ordered. The updated estimate that such an improvement process could offset the estimated burden on Medicare beneficiaries by $27,394,759 annually for an incremental change (reduction) of $6,605,741.

c. Impact on Transmitting Orders for Advanced Diagnostic Imaging Services

In the CY 2019 PFS final rule, we estimated that including AUC consultation information on the order for an advanced diagnostic imaging service to the furnishing professional or facility is estimated as the additional 5 minutes spent by a medical secretary (occupation code 43–6013). To update this estimate, we use the May 2020 mean hourly wage of $18.75 plus 100 percent fringe benefits to transmit the order for the advanced diagnostic imaging service. In aggregate, we assumed in the CY 2019 PFS final rule that 40,000,000 advanced diagnostic imaging services are ordered annually. We propose to update that number to match the total number of AUC consultations proposed earlier in this RIA to 30,359,901, so the updated total annual burden to communicate additional information in the order is estimated as $94,495,192 ($18.75/hr × 2 × 0.083 hr × 30,359,901 orders) for an incremental change (reduction) of $20,044,808.

d. Impact on Furnishing Professionals and Facilities

As described in the CY 2019 PFS final rule, we identified an estimated 174,064 furnishing professionals (comprising radiologists, ASCs, IDTFs and hospitals) and assumed that every identified furnishing professional will choose to update their processes for the purposes of the AUC program in the same way by purchasing an automated solution to report AUC consultation information which was estimated to cost $10,000 for each furnishing professional. We update this cost to account for inflation and therefore the updated estimated cost is $10,636.07 ($10,000 adjusted for inflation to 2021 dollars) for a total estimated one-time update cost of $1,851,356,888.48 (174,064 × $10,636.07).

e. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

As described in the CY 2019 PFS final rule, we assumed that there may be some savings to the Medicare program due to the AUC program requirements

and potential decreases in inappropriate utilization of advanced diagnostic imaging services. This assumption was based on literature describing prior experiences with clinical decision support in a pilot project conducted in Minnesota, a retrospective cohort study on evidence-based clinical decision support for lumbar MRI, brain MR and sinus CT and local implementation of clinical decision support, and we estimated that savings may account for $700,000,000 savings per year.

f. Summary of Delay-Attributable Changes and Discounted Rates

Table 125 summarizes the substantive changes from the CY 2019 PFS final rule to the CY 2022 PFS proposed rule impact estimates. The effect of a 3-year delay is approximated by applying 3 years' worth of discounting at 7 percent or 3 percent discount rates (Circular A–4, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/regulatory_matters_pdf/a-4.pdf*).

TABLE 125: AUC Program Related Activities with Changes in Impact Estimates Resulting from a Three-Year Delay

AUC Program Related Activity	CY 2022 PFS Proposed Rule Impact Estimate	Change from CY 2019 PFS Final Rule (as a function of the discount rate)
Impact of required AUC consultations by ordering professional	$51,039,109	- $4.3 million (3%) - $9.4 million (7%)
Impact to Medicare beneficiaries	$54,789,518	- $4.6 million (3%) - $10.1 million (7%)
Impact on transmitting orders for advanced diagnostic imaging services	$94,495,192	- $8.0 million (3%) - $17.4 million (7%)
AUC automated solution	$1,851,356,888	- $157.1 million (3%) - $340.1 million (7%)
Medicare program impacts associated with advanced diagnostic imaging services	$700,000,000	- $59.4 million (3%) - $128.6 million (7%)
Total Change Attributable to a Three-Year Delay		- $174.1 million (costs, 3%) - $376.9 million (costs, 7%) - $59.4 million (transfers, 3%) - $128.6 million (transfers, 7%)

5. Proposal To Remove Select National Coverage Determinations (NCDs)

We are proposing to remove two older NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. Generally, proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. The two NCDs fall into two impact categories. First, eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous national coverage determination barred coverage for an item or service under title XVIII, MACs would now be able to cover the item or service if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within these policies will be limited, each affecting less than one percent of the Medicare FFS population.

For the one NCD where we are proposing to go from limited coverage to MAC discretion, claims data from 2019 shows that less than one percent of the Medicare population is affected. Specifically, we provide coverage with limitations for enteral nutrition and parenteral nutrition therapy under NCD 180.2, where in 2019 CMS paid 1,643,739 Medicare FFS claims for 83,551 unique beneficiaries totaling CMS payments of $356,228,606. While we have claims data available for 2020, the data shows a decrease in claims, unique beneficiaries and total amount paid by CMS. We believe this may be due in part to the COVID–19 pandemic; however, we do not have any information to be able to say that conclusively. The change could be due to other factors not examined here. We estimate there will be de minimis change to 2022 payments, compared to 2019 or 2020 because, as discussed in section III.F. of the proposed rule, local contractors have proposed LCDs that, if finalized, would provide parenteral and enteral nutrition coverage for certain Medicare beneficiaries. Therefore, we believe that removing this NCD would not result in significant changes to payments.

For the one non-covered NCD proposed to be eliminated, Positron Emission Tomography (PET) Scans under NCD 220.6, we would not expect to find historical claims data for the non-oncologic uses of PET at issue. We broadly noncover non-oncologic indications of PET, in other words, we required that every non-oncologic indication for PET must have its own NCD in order to receive coverage. Because this NCD provides for noncoverage on non-oncologic indications, we do not have accurate claims data to estimate total impact. However, based on the service, we expect future claims to affect less than one percent of Medicare FFS

beneficiaries. As discussed in section III.F. of this proposed rule, the NCD allows coverage for diagnostic PET imaging for oncologic uses not already determined by an NCD, to be made at the discretion of local MACs. We believe that extending local contractor discretion for non-oncologic indications of PET provides an immediate avenue to potential coverage in appropriate candidates and provides a framework that better serves the needs of the Medicare program and its beneficiaries. For clarity, we are not proposing to change any other subsections of 220.6. Thus, the NCDs listed at 220.6.1 through 220.6.20 would not be changed by this proposal.

6. Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation

As discussed in section III.H., Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR), of this proposed rule, we are proposing largely conforming changes throughout §§ 410.47 (PR) and 410.49 (CR/ICR). These changes are intended to ensure consistency and accuracy in terminology, definitions and requirements where appropriate across PR and CR/ICR conditions of coverage. Specific to PR, we are proposing to remove the requirement for direct physician-patient contact related to the periodic review of the patient's treatment plan because such interaction within the PR program is not necessary for all patients and can be specified, as needed, in individualized treatment plans (ITPs). We are also proposing to add coverage of PR for beneficiaries who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge.

In assessing the impact of these proposals, we note that the proposed expansion of PR coverage may increase utilization. Based on the low utilization rate discussed below, we do not believe the other proposed revisions will significantly impact utilization and the Medicare program.

To estimate the potential increase from the proposed expansion of coverage for PR, we searched the literature for articles that evaluated the utilization rate of PR for the currently eligible diagnosis of chronic obstructive pulmonary disease (COPD) in order to determine the historical utilization trends of this service.

Nishi et al. (2016) investigated the number of Medicare beneficiaries with COPD who received PR from January 1, 2003 to December 31, 2012. Their results included both individuals who had experienced hospitalizations for COPD and those who were outpatients only. The number of unique patients with COPD who initially participated in PR during the study period was 2.6 percent in 2003 (before conditions of coverage at § 410.47 were established) and 2.88 percent in 2012 (after conditions of coverage at § 410.47 were established).[252] In 2019, Spitzer, et al. published an article based on Medicare claims data from 2012, finding that 2.7 percent of eligible Medicare beneficiaries received PR within 12 months of hospitalization with COPD.[253] Using claims data from fee-for-service Medicare beneficiaries hospitalized for COPD in 2014, Lindenauer et al. (2020) reported that only 3 percent initiated PR within 1 year of their hospital discharge.[254] Taken together, this data informs us that utilization of PR in the Medicare population is very low, and that the majority of patients who avail themselves of this service do so, post hospitalization.

There are limitations to applying this data to identify the utilization rate of PR to the conditions of coverage specified at § 410.47. Most notably, some of these studies included patients whose services were billed with non-PR respiratory therapy codes (G0237, G0238 and G0239), instead of only patients whose services were billed with the PR code (G0424). But the authors also limited patient inclusion to those with a principal or secondary COPD diagnosis, so we believe this suggests that 3 percent is an upper bound for the utilization of PR currently in Medicare beneficiaries. Given that participation in PR has remained steady for many years, we do not expect this pattern to change. As such, for the purposes of this analysis, we assume that 3 percent of eligible beneficiaries under the proposed expansion of coverage (hospitalized with COVID–19 and experiencing persistent symptoms, including respiratory dysfunction, for at least 4 weeks after discharge) will participate in PR.

To identify the eligible beneficiaries under our proposal, we first identify the number of beneficiaries hospitalized with COVID–19 using the Preliminary Medicare COVID–19 Data Snapshot.[255] At the time of writing, the Snapshot included data from January 1, 2020 to March 20, 2021, and identified 1,141,592 total COVID–19 hospitalizations for Medicare beneficiaries. The Snapshot indicates that 18 percent of these patients expired so we reduce this number by 18 percent to 936,105 beneficiaries. A paper published by the Tony Blair Institute for Global Change [256] states that the Covid Symptom Study led by King's College London indicated that about 10 percent of survey participants reported symptoms (including shortness of breath and other symptoms like fatigue, headache and loss of smell) beyond a four-week recovery period. Using this information we estimate that the patient population we are proposing to expand PR coverage to, those who were hospitalized with a COVID–19 diagnosis and experienced persistent symptoms, including respiratory dysfunction, for at least 4 weeks after hospital discharge, to be 93,611 beneficiaries (936,105 × 0.10). Based on our assumption of utilization above, 3 percent, for the newly proposed covered patient population, we estimate 2,808 beneficiaries will receive PR (93,611 × 0.03).

Medicare covers PR for a maximum of 72 sessions. Using 2018 and 2019 Medicare claims data from the Chronic Conditions Data Warehouse (CCW), beneficiaries on average completed 14 sessions of PR. If we assume patients eligible based on our proposed expansion of coverage would participate, on average, in the same number of sessions, we estimate the proposed expansion of coverage will increase PR utilization by 39,312 sessions annually (2,808 beneficiaries × 14 average sessions completed per beneficiary).

Claims for PR are submitted using CPT code G0424. Our analysis of Medicare claims data indicates that 97.54 percent of PR sessions are billed under the Hospital OPPS at $55.66 (national average price) for an estimated total of $2,134,279 (39,312 PR sessions × 0.9754 × $55.66). The remaining 2.46

[252] Nishi SP, Zhang W, Kuo YF, Sharma G. Pulmonary Rehabilitation Utilization in Older Adults With Chronic Obstructive Pulmonary Disease, 2003 to 2012. J Cardiopulm Rehabil Prev. 2016;36(5):375–382. doi:10.1097/HCR.0000000000000194.

[253] Spitzer KA, Stefan MS, Priya A, et al. Participation in pulmonary rehabilitation after hospitalization for chronic obstructive pulmonary disease among Medicare beneficiaries. Ann Am Thorac Soc. 2019;16:99–106.DOI: 10.1513/AnnalsATS.201805–332OC. PMID: 30417670; PMCID: PMC6344454.

[254] Lindenauer PK, Stefan MS, Pekow PS, et al. Association Between Initiation of Pulmonary Rehabilitation After Hospitalization for COPD and 1-Year Survival Among Medicare Beneficiaries. JAMA. 2020;323(18):1813–1823. doi:10.1001/jama.2020.4437.

[255] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[256] Published at *https://institute.global/sites/default/files/articles/Long-Covid-Reviewing-the-Science-and-Assessing-the-Risk.pdf* on October 5 2020.

percent of PR sessions are billed under the PFS, with 2.12 percent of PR sessions furnished in a physician's office which has a national average price of $30.36 and 0.34 percent billed by a physician when PR was furnished in a hospital outpatient department which has a national average price of $13.96. Taken together, the estimated total for this remaining 2.46 percent of PR sessions is $27,168 ((39,312 PR sessions × 0.0212 × $30.36) + (39,312 PR sessions × 0.0034 × $13.96)). We estimate the total added cost to the Medicare program of this proposed expansion of coverage to be $2,161,447 ($2,134,279 + $27,168) annually during and immediately following the public health emergency (PHE) for COVID–19. As hospitalizations and COVID–19 cases decline, we expect the annual impact to decrease because eligible patient populations will likely decrease, however we are unable to estimate the longer term impact of our proposals due to the unpredictable nature of the PHE and the lack of long term data on COVID–19.

7. Medical Nutrition Therapy

As discussed in section III.I., Medical Nutrition Therapy (MNT), of this proposed rule, we are proposing to remove the restriction that patients only be referred to MNT by the treating physician and update the glomerular filtration rate (GFR) eligibility for patients with chronic kidney disease. We do not anticipate any significant increase in utilization of MNT services resulting from our proposed revisions. Despite various policy changes that could have improved use, such as increasing payment via adding work RVUs to MNT codes in 2006, approving MNT for telehealth coverage in 2005 and including registered dieticians (RDs) and nutrition professionals as telehealth distant site providers, and waiving out-of-pocket costs to beneficiaries, MNT participation remains under 2 percent of eligible beneficiaries. Based on an analysis of Medicare claims data from 2018, 2019, 2020, we identify the utilization rate of MNT services among eligible beneficiaries to be between 1.5 and 1.8 percent.

Although MNT is covered by many state Medicaid programs and private insurers, use is low in the US.[257] [258] [259] The Academy of Nutrition and Dietetics recognizes that research specific to the underuse of MNT services is scant.[260] Anecdotal reports and related research on diabetes self-management training point to a multitude of reasons why utilization of the MNT services benefit have remained low. These potential barriers include lack of awareness of MNT by patients and clinicians, inconsistent coverage for MNT services by non-Medicare payers, patient travel and time issues to receive the services and lack of availability of services from RDs who may perceive the process of Medicare enrollment/insurance credentialing and billing as being burdensome and complex.[261] Of about 100,000 RDs in the US, only 1,589 submitted Medicare fee-for-service MNT claims in 2017. One study revealed that less than half of RDs providing MNT services in an ambulatory care setting indicated they were not Medicare providers due to reasons such as perceived low reimbursement rates, not providing MNT to Medicare eligible patients, not knowing how to become a Medicare provider, and providing MNT to Medicare patients for diagnoses not covered by Medicare.[262]

Our proposed revisions may increase beneficiary access to the MNT benefit and reduce primary care physician burden since we are proposing that referrals can come from other physicians and not only from the physician treating the patient for their diabetes or kidney disease; although, as discussed above, we do not expect the changes to make a significant impact on the Medicare program. We do not anticipate increased administrative burden as documentation in the medical record of any referred service is already a part of discharge planning in the hospital setting. The proposed changes to the GFR requirements are to conform our regulation to updated clinical standards and also do not pose a significant change.

8. Medicare Shared Savings Program

a. Modifications to the Shared Savings Program Quality Reporting Requirements Under the APP and the Quality Performance Standard

In section III.J.1.d. of this proposed rule, we are proposing to freeze the quality performance standard at the 30th percentile MIPS Quality Performance Category Score for performance year 2023, increasing to the 40th percentile MIPS Quality performance category score in performance year 2024. Without this proposed change, the quality standard would have increased to the 40th percentile in 2023. The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions.

Our analysis of quality performance data reported by ACOs for performance years starting during 2019 indicates that about 20 percent of ACOs would have failed a quality performance standard defined as the 40th percentile across all MIPS Quality performance category scores as would apply for PY 2023 without the proposed 1-year delay. There is significant uncertainty whether PY 2023 would play out similarly to the baseline data. The fraction of ACOs ultimately failing to meet a higher standard in PY 2023 could change significantly if the universe of MIPS Quality performance category scores improves relative to ACOs' quality performance scores, or alternatively if ACOs, particularly ACOs at risk of failing, respond to the increased quality performance standard by boosting their performance. Utilizing a Monte Carlo approach, assuming that the simulated poor performing ACOs have a 50 percent chance of improving their quality performance beyond the 40th percentile, if CMS kept the quality performance standard at the 40th percentile, then the cost of reducing to the 30th percentile in 2023 would be $190 million (range $10 million to $370 million). There is a wide range because slight changes in quality scoring at the low end of the distribution could render the 40th percentile more or less of an effective point of discrimination among ACOs earning shared savings.

In addition, in section III.J.1.c. of this proposed rule, we are proposing an update to the quality reporting requirements under the APM

[257] *https://www.eatrightpro.org/payment/nutrition-services/medicaid/medicaid-and-rdns*

[258] Kramer, H., Jimenez, E.Y., Brommage, D., Vassalotti, J., Montgomery, E., Steiber, A., & Schofield, M. (2018). Medical nutrition therapy for patients with non-dialysis-dependent chronic kidney disease: barriers and solutions. *Journal of the Academy of Nutrition and Dietetics*, 118(10), 1958–1965.

[259] Jimenez, E.Y., Kelley, K., Schofield, M., Brommage, D., Steiber, A., Abram, J. K., & Kramer, H. (2021). Medical nutrition therapy access in CKD: A cross-sectional survey of patients and providers. Kidney medicine, 3(1), 31-41.

[260] Kramer, H., Jimenez, E.Y., Brommage, D., Vassalotti, J., Montgomery, E., Steiber, A., & Schofield, M. (2018). Medical nutrition therapy for patients with non–dialysis-dependent chronic kidney disease: barriers and solutions. Journal of the Academy of Nutrition and Dietetics, 118(10), 1958–1965.

[261] Ibid.

[262] Parrott JS, White JV, Schofield M, Hand RK, Gregoire MB, Ayoob KT, Pavlinac J, Lewis JL, Smith K. Current coding practices and patterns of code use of registered dietitian nutritionists: The Academy of Nutrition and Dietetics 2013 coding survey. J Acad Nutr Diet. 2014;114(10):1619–1629.

Performance Pathway or APP for performance years 2022 and 2023.

For performance year 2022: An ACO would be required to report on either

(a) The ten CMS Web Interface measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP, or

(b) The three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP. If an ACO selects this option, meets the data completeness at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQM/MIPS CQM measures, and achieves a quality performance score equivalent to or higher than the 30th percentile on at least one measure in the APP measure set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year. If an ACO chooses this option, its performance on all six measures in the APP measure set would be used for purposes of MIPS scoring under the APP. If an ACO decides to report both the ten CMS Web Interface measures and the three eCQM/MIPS CQM measures, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

For performance year 2023: An ACO would be required to report on either:

(a) The ten CMS Web Interface measures and at least one eCQM/MIPS CQM measure and administer a CAHPS for MIPS survey and CMS would calculate the two claims-based measures included under the APP or

(b) The three eCQM/MIPS CQM measures and administer a CAHPS for MIPS survey and CMS would calculate the two claims based measures included under the APP. If an ACO selects this option, meets the data completeness requirement at § 414.1340 and the case minimum requirement at § 414.1380 for all three eCQM/MIPS CQM measures, and achieves a quality performance score equivalent to or higher than the 30th percentile on one measure in the APP measure set, the ACO would meet the quality performance standard used to determine eligibility for shared savings and to avoid maximum shared losses, if applicable, for that performance year. If an ACO chooses this option, its performance on all six measures in the APP measure set would be used for purposes of MIPS scoring under the APP. If an ACO decides to report both the ten CMS Web Interface measures and the three eCQM/MIPS CQM measures, it will receive the higher of the two quality scores for purposes of the MIPS Quality performance category.

If an ACO does not report at least one eCQM/MIPS CQM measure the ACO would not meet the quality performance standard.

Absent the related proposal analyzed above to reduce the performance standard to the 30th percentile MIPS Quality performance category score, the proposed changes to the quality reporting requirements, including the accommodation to continue the availability of the CMS Web Interface as a reporting mechanism under the APP would have likely provided an easier path for a meaningful subset of ACOs that would have otherwise faced difficulty meeting the quality threshold previously established in rulemaking for PY 2023. However, we estimate that nearly all such ACOs would already meet the lower 30th percentile performance standard in PY 2023 without the additional reporting flexibility. Of the relatively few, remaining ACOs, that we estimate would fail to meet the proposed lower 30th percentile performance standard, we estimate that about half (on average) would meet the quality performance standard as a result of the proposed quality reporting flexibility, and thereby further increase shared savings payments to ACOs by about $20 million in PY 2023.

b. Modifications to Other Shared Savings Program Requirements

We do not anticipate a material aggregate impact for the other changes we are proposing related to the Shared Savings Program, specifically: revisions to the definition of primary care services used in the Shared Savings Program's beneficiary assignment methodology (section III.J.2. of this proposed rule); revisions to the repayment mechanism arrangement policy, including changes to the calculation and recalculation of repayment mechanism amounts (section III.J.3. of this proposed rule); revision of the requirements concerning disclosure of prior participation in the Shared Savings Program by the ACO, ACO participants, and ACO providers/suppliers, and revisions to Shared Savings Program requirements to reduce the frequency and circumstances under which ACOs submit sample ACO participant agreements and executed ACO participant agreements to CMS (section III.J.4. of this proposed rule); and revisions to the beneficiary notification requirement as it applies to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation (section III.J.5. of this proposed rule).

However, as we note in section III.J.3. of this proposed rule, lower required repayment mechanism amounts could reduce costs for ACOs in fees charged by financial institutions for letters of credit and by insurance companies for surety bonds. We estimate that such relief, in total for all participating ACOs, could be worth $2 to $4 million annually under the proposed approach (assuming a reduction of approximately $196 million in repayment mechanism amounts, in aggregate) and $3 to $6 million annually under the second, alternative option (assuming a reduction of approximately $322 million in repayment mechanism amounts, in aggregate).

We also note that the proposed revisions to the definition of primary care services used in the assignment methodology may have differing effects on a subset of participating ACOs, for example by changing the competing ACO to which a beneficiary ultimately is assigned, for a small subset of beneficiaries. We do not anticipate such ACO-level changes would result in a net impact on program spending overall.

9. Medicare Ground Ambulance Data Collection System

In section III.K. of this proposed rule, we propose a series of changes to the Medicare Ground Ambulance Data Collection System including the proposed change to the data collection period and data reporting period for selected ground ambulance organizations in year 3, proposed revisions to the timeline for when the payment reduction for failure to report will begin and when the data will be publicly available, and proposed revisions to the Medicare Ground Ambulance Data Collection Instrument.

While we believe that these changes and clarifications will be well received by the ground ambulance stakeholders, we do not believe that these changes would have any substantive impact on the cost or time associated with completing the Medicare Ground Ambulance Data Collection Instrument. We note that the overall length of the Medicare Ground Ambulance Data Collection Instrument is the same as previously finalized (84 FR 62888) with these changes. Additionally, some of the

instructions which we propose to add are intended to improve clarity and may therefore reduce the time the ground ambulance organizations spend addressing the questions.

10. Medicare Diabetes Prevention Program Expanded

a. Effects of Proposals Relating to the Medicare Diabetes Prevention Program Expanded Model

(1) Effects on Beneficiaries

We propose to modify certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to: (1) Allow CMS to remove the ongoing maintenance phase (months 13–24) of the MDPP set of services for those beneficiaries who started their first core session on or after January 1, 2022; (2) update the performance payments for the MDPP set of services in the core and core maintenance performance periods; and (3) waive the Medicare provider enrollment application fee for all organizations enrolling as MDPP suppliers on a prospective basis. These proposed changes will have a positive impact on beneficiaries' health by increasing the capacity of MDPP eligible organizations to enroll in Medicare as MDPP suppliers and increasing access to the MDPP set of services to beneficiaries. Eligible beneficiaries receive these services as preventive services, which require no copays or cost sharing. These proposed changes address MDPP supplier and beneficiary needs based upon all available monitoring and evaluation data. The proposed changes are also responsive respond to stakeholder comments.

(2) Effects on the Market

Currently, more than 1,000 organizations nationally are eligible to become MDPP suppliers based on their preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) status. However, only 27 percent of eligible organizations are participating in MDPP. We anticipate that the removal of the second year of the MDPP set of services will make MDPP attractive and feasible to more MDPP eligible organizations. Not only does a 12-month MDPP services period align with that of the CDC's National DPP and the DPP model test, our data show that only 10 percent of enrolled MDPP participants continue with the Ongoing Maintenance phase sessions (Year 2), and the majority are reaching their weight loss milestone within the first 6 months of the set of MDPP services. Stakeholders report that the second year of MDPP, or the ongoing maintenance phase, is cost prohibitive due to the costs to retain beneficiaries in year 2 of the expanded model as well as the costs to deliver an additional year of the expanded model that is not supported by the CDC National DPP curriculum. The CDC's National DPP curriculum supports a 1-year program and suppliers have found it difficult to extrapolate the curriculum to a second year. Additionally, MDPP suppliers commented that they have an increasingly difficult time making the business case for MDPP given the costs associated with the ongoing maintenance phase and the low performance payments associated with the second year. Given the low volume of participants continuing in the second year of MDPP, delivering the MDPP ongoing maintenance period creates an undue burden to MDPP suppliers. The cost to offer and deliver the sessions to a small cohort of individuals outweigh the maximum payments available from Medicare.

Stakeholders have consistently commented that CMS should shorten the MDPP expanded model to 1 year, with payment levels at least equivalent to the levels provided in the DPP model test. For example, during the DPP model test, suppliers were paid an average of $462 per beneficiary for the 1-year model test. The second year has made delivering MDPP both financially unattractive and unstainable for many of the current and eligible MDPP suppliers. Suppliers have reported that it is very difficult to engage and retain beneficiaries in a second year, and the reimbursement levels for a second year are inadequate to cover supplier costs. Since a second year of the MDPP deviates from both the DPP model test and the National DPP clinical trial protocol, we propose to shorten the MDPP service period to 1 year and increase the performance payments in the first year. These changes respond to stakeholder feedback and may alleviate some of the difficulty retaining MDPP participants during the core maintenance phase of the program.

(3) Burden Related to Information Collection Requirements—No Impact

(a) Supplier Standards

MDPP suppliers may encounter the Medicare enrollment fee during the following Medicare provider enrollment transactions: Initial enrollment, revalidation (every 5 years for MDPP), or the addition of a new practice location. The provider/supplier enrollment fee for Calendar Year 2021 is $599. Although MDPP suppliers may submit a written request to CMS for a hardship exception to the application fee in accordance with § 424.514, many would not qualify and the hardship application process would simply add more burden on the organization. We have heard from the CDC as well as other stakeholders that the enrollment fee is a potential barrier to eligible MDPP suppliers who would not otherwise enroll in Medicare except for MDPP. Approximately 39 percent of our current suppliers are non-traditional suppliers that serve their local communities and play a critical role in enrolling more diverse, equitable, and inclusive cohorts of Medicare beneficiaries to MDPP. These non-traditional suppliers include, but are not limited to YMCAs, county health departments, community health centers, and non-profit organizations that focus on health education, and otherwise would neither enroll nor be able to enroll as a Medicare supplier at all if it were not for MDPP. They often serve as trusted sources of health information for their communities. However, they also represent a large number of eligible organizations who have not enrolled in Medicare as MDPP suppliers. We anticipate that waiving the enrollment fee along with the other programmatic adjustments are likely to result in more MDPP suppliers, increased beneficiary access to MDPP services, and an ongoing reduction of the incidence of diabetes in eligible Medicare beneficiaries, in both urban and rural communities.

In April 2020, CMS waived all provider enrollment application fees as part of the COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers. As a result, we saw an increase in MDPP supplier enrollment. We believe that granting a permanent waiver of the fee for MDPP suppliers to extend beyond the COVID–19 Emergency Declaration Blanket Waiver, along with the other proposed change to MDPP, may stimulate MDPP supplier enrollment and enhance the MDPP evaluation. We propose waiving the Medicare provider enrollment fee beyond COVID–19 Emergency Declaration Blanket Waivers for Health Care Providers because the enrollment fee creates a potential barrier to MDPP supplier enrollment, beneficiary access to the program, and subsequently, our ability to evaluate MDPP. Specifically, we propose, to waive the enrollment fee as described in section 1866(j)(2)(C)(i) and (ii) of the Act during the MDPP expanded model test phase.

(b) Payment for MDPP Services

Our regulations at § 414.84 specify the payments MDPP suppliers may be eligible to receive, payments for

furnishing MDPP services, and meeting performance targets related to beneficiary weight loss and/or attendance. MDPP suppliers are paid by CMS by submitting claims for MDPP beneficiaries using claim form CMS–1500 (*https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf*). As a condition for payment, claims submitted by MDPP suppliers must be for services furnished to eligible beneficiaries in accordance with § 414.84(b) and (c). We have streamlined the proposed performance payments so that they are easier to understand and suppliers receive larger payments for participants reaching attendance and weight loss performance-based milestones. For example, the proposed attendance-based performance payments are based on a standardized per-session rate, paid after the 1st, 4th, and 9th sessions attended during the core sessions interval, and after attending the two (2) sessions during each of the core maintenance intervals. We have increased performance payments for beneficiary achievement of the 5 percent weight loss goal as well as continued attendance during the core maintenance intervals. Although the proposed maximum payment of $661 over a 1-year service period is less than the current maximum payment of $704 under the original 2-year payment structure, we believe eliminating the second year and its associated payments while increasing the first year payments will result in a financially sustainable expanded model.

Increasing the first year MDPP payment amounts should not negatively affect a supplier's performance (for example, participants' weight loss). The increase to the payment amounts are not applied until after the 4th core session and the largest payments to suppliers are still driven by weight loss achievement. Further, in order to maintain CDC Diabetes Prevention Recognition Program (DPRP) recognition status, which is required to be an MDPP supplier, certain levels of performance metrics (for example, weight loss) must be satisfied. There is no evidence that eliminating the second year maintenance sessions, shortening the MDPP services period to 1 year, will have any negative effects on performance.

(4) Effects on the Medicare Program

(a) Estimated 10-Year Impact of MDPP

Table 126 shows estimates (in millions) for the impact on Medicare spending of two proposed changes to the Medicare Diabetes Prevention Program (MDPP) to be implemented in 2022:

- Waiving the Medicare enrollment fee for all new MDPP suppliers; and
- Shortening the MDPP services period to 1 year and shifting some of the Ongoing Maintenance reimbursement amounts to year one.

TABLE 126: Estimated 10-Year Impact of MDPP on Medicare Spending for CYs 2022 through 2031

Year	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	Total
Impact on Medicare Spending	$0.2	$0.2	$0.1	$0.0	-$0.1	-$0.2	-$0.2	-$0.3	-$0.3	-$0.4	-$0.9

These estimates by the CMS Office of the Actuary do not consider waiving the Medicare enrollment fee as a direct cost and assume there will be an additional 500 beneficiaries per year participating in MDPP. In the most recent year prior to the Public Health Emergency (PHE), 1,742 Medicare beneficiaries entered MDPP. Increasing the first year payment amounts to suppliers and waiving the Medicare enrollment fee should increase access to MDPP, resulting in more utilization of the MDPP set of services. Starting in 2022, we can assume that 2,000 beneficiaries would have entered the program each year without including the proposed changes. After including these changes, we will now assume 2,500 beneficiaries will enter the program each year. This assumption has a high level of uncertainty and we revisit it in the Sensitivity Analysis section.

(b) Sensitivity Analysis

Since the cost to suppliers for delivering the MDPP set of services is generally unknown, how utilization of the expanded model will be affected by the proposed changes is highly uncertain. Table 127 shows the 10-year impact estimates (in millions) for different levels of additional beneficiary participation as a result of the proposed changes:

TABLE 127: 10 Year Impact Estimates

Additional Beneficiaries Per Year	10-year Estimated Impact
0	$0.5
500 (assumption used in best estimate)	-$0.9
1,000	-$2.3
1,500	-$3.7

Finally, higher projected savings are associated with increases in beneficiary participation, while no additional beneficiaries would result in an estimated cost.

b. Alternatives Considered

No alternatives were considered. The 2-year MDPP service period has depressed interest in MDPP among would-be MDPP suppliers. These proposed actions address stakeholder comments on the barriers to MDPP expanded model success. If we do not take action, we will not be able to scale MDPP as intended, impacting Medicare beneficiary access to this expanded model. Reducing the MDPP from a 24- to a 12-month services period, increasing the year 1 performance payments, and waiving the Medicare provider enrollment application fee not

only better aligns the expanded model with the evidence that helped certify the DPP model test initially, but it will encourage eligible organizations to enroll as MDPP suppliers.

c. Impact on Beneficiaries

This change will have a positive impact on eligible MDPP beneficiaries, as it better aligns with the CDC's National DPP, giving both the participants and the coaches similar messaging around this program, regardless of payer. MDPP suppliers often offer the MDPP set of services to mixed cohorts, or classes with participants who are not eligible for MDPP, but who are enrolled in a National DPP cohort. Since MDPP generally follows the CDC's National DPP and aligns its expanded model with the CDC's DPRP Standards, it is confusing to participants, coaches, and staff when talking about a 2-year set of services to its eligible Medicare participants when the non-Medicare participants have a 1-year program. Finally, reducing the MDPP service period from 2 years to 1 year allows more cohorts to start and finish MDPP during the expanded model initial period of performance, which ends in March 2023.

d. Estimating Regulatory Familiarization Costs

Given that we tried to align this rule as much as possible with the CDC DPRP Standards, there should be minimal regulatory familiarization costs. This rule impacts only enrolled MDPP suppliers and eligible beneficiaries who have started the MDPP expanded model or are interested in MDPP.

11. Medicare Provider and Supplier Enrollment Changes—Provider Enrollment

As explained in section III.N. of this proposed rule, we propose changes to three of our existing revocation reasons:

- We propose to expand § 424.535(a)(2) to permit revocation based on the OIG exclusion of an individual serving in an administrative or management services role for the provider/supplier, such as a billing specialist, accountant, or human resources specialist.
- We propose to expand § 424.535(a)(13) to permit revocation of a physician's or other eligible professional's enrollment if he or she surrenders his/her Drug Enforcement Administration (DEA) certificate of registration in response to an order to show cause.
- We propose to revise the factors in § 424.535(a)(8)(ii) (which permits revocation based on a pattern or practice of submitting non-compliant claims) to better enable CMS to target shorter periods of non-compliant billing.

We believe that all three of these changes would result in an increase in the number of revocations that CMS imposes. However, we believe this number will be rather small. We currently impose only a limited number of revocations under §§ 424.535(a)(2), (a)(13), and (a)(8). Accordingly, since our expansion of these three revocation reasons would be fairly modest, we do not foresee more than a very slight increase in revocations thereunder.

Table 128 outlines the number of revocations we estimate would ensue under our proposed revocation expansions. These numbers only account for additional revocations stemming from our changes:

TABLE 128: Additional Revocations

Revocation Reason	Number
§ 424.535(a)(2)	5
§ 424.535(a)(13)	5
§ 424.535(a)(8)(ii)	5
Total	**15**

Internal CMS data indicates that the average provider/supplier that would be affected by these regulatory expansions receives roughly $50,000 in Medicare payments each year. (We used a similar $50,000 annual payment estimate for our provider enrollment provisions in the CY 2020 PFS final rule) (84 FR 62568)). Providers/suppliers revoked under our proposed revocation expansions would thus not receive these payments. Hence, multiplying our $50,000 estimate by the revocation totals in Table 128 results in a projected transfer from these providers/suppliers to the federal government of $750,000 ($50,000 × 15 revocations).

12. Provider/Supplier Medical Review Requirements—Prepayment and Post-payment Reviews

In section III.N.2. of this proposed rule, we are proposing to: (1) Define key terms including ''additional documentation,'' ''additional documentation request,'' ''post-payment medical review,'' and ''prepayment medical review;'' (2) codify contractors' authority to request additional documentation for prepayment and post-payment review within established timeframes; (3) codify timeframes for response to requests for documentation; and (4) codify result of a failure to comply with prepayment or post-payment documentation request(s) by a provider or supplier, specifically denial of payment. We do not believe these proposals involve any additional impact or burden on providers, suppliers, or states; however, we welcome feedback from stakeholders regarding the potential costs of these proposals.

The proposed regulations would incorporate already established key terms and definitions as well as processing requirements pertaining to prepayment and post-payment medical review into regulation. Although placing this information in regulation could improve provider and supplier understanding of the medical review process and their responsibilities in complying with our review contractor's requests, the proposed regulations represent no change to medical review requirements. As such, we do not anticipate any change in the number of prepayment medical reviews, post-payment medical reviews or the number of additional documentation requests made by contractors.

13. Effect of Proposed Modifications to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

As discussed in section III.O of this proposed rule, we are proposing to allow OTPs to continue to furnish the therapy and counseling portions of the weekly bundles, as well as any additional counseling or therapy that is billed using the add-on code, using audio-only telephone calls rather than via two-way interactive audio-video communication technology in cases

where audio/video communication is not available to the beneficiary after the conclusion of the PHE for COVID–19, provided all other applicable requirements are met.

We believe the Part B cost impact of this proposal would be minimal, since payment for therapy and counseling is included in the bundled payment regardless of the modality used to deliver it and we do not expect that this proposal would increase the frequency at which medically necessary counseling and therapy services are billed using the counseling and therapy add-on code (HCPCS code G2080). However, we are also proposing to require that when these services are furnished using audio-only technology, practitioners certify that they had the capacity to furnish the services using two-way audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary. We believe this proposed change would facilitate broader access to these services for beneficiaries.

Additionally, as discussed in section III.O. of this proposed rule, the FDA recently announced the approval of a new, higher dose naloxone hydrochloride nasal spray product used to treat opioid overdose and that the newly approved product delivers 8mg of naloxone. In the CY 2021 PFS final rule (85 FR 84683 through 84685), we finalized payment for HCPCS code G2215 (Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure). HCPCS code G2215 was priced based on an assumption of a typical case in which the beneficiary would be provided with a box of two 4mg nasal spray products. At the time of drafting this proposed rule, we do not yet have any available pricing information for this newly approved product. However, in order to be able to make payment to OTPs under Medicare for this product, we are proposing to create a new G-code describing a take-home supply of this higher dose naloxone hydrochloride nasal spray product. Since pricing information is unavailable for this new product at the time of drafting this proposed rule, the estimated cost impact is unclear at this time, however, we believe utilization would be low based on CY 2021 claims data received so far for HCPCS code G2215.

14. Physician Self-Referral Update

The physician self-referral law provisions are discussed in section III.P. of this proposed rule.

As discussed in section III.P. of this proposed rule, we are proposing to amend the provisions of § 411.354(c)(2) identifying unbroken chains of financial relationships that constitute ''indirect compensation arrangements'' to ensure that a long-standing prohibition on certain per-unit of service compensation formulas for determining charges for the rental of office space and equipment remains within the ambit of the law. This provision, which was inadvertently omitted when the definition of ''indirect compensation arrangement'' was revised in the December 2, 2020 final rule entitled ''Modernizing and Clarifying the Physician Self-Referral Regulations'' (85 FR 77492), is necessary to protect against potential abuses such as overutilization and anti-competitive behavior. We believe that most parties have continued to comply with the regulatory provisions on per-unit of service compensation formulas for the rental of office space and equipment as they have done since the requirements became effective on October 1, 2009. In response to stakeholder inquiries, we are also proposing to add provisions to assist stakeholders in identifying the individual unit to be analyzed under the provisions of § 411.354(c)(2)(ii)(A)(i) through (iii) and proposed § 411.354(c)(2)(ii)(A)(iv). We believe that the clarity provided by this proposal would facilitate compliance without adding burden.

As discussed in section III.P. of this proposed rule, we are proposing to permit the use of the exception for preventive screening tests, immunizations, and vaccines at § 411.355(h) for COVID–19 vaccines even when they are not subject to CMS-mandated frequency limits, provided that all other requirements of the exception are satisfied. We believe that this proposal would ensure that the physician self-referral law would not impede the availability of critically important COVID–19 vaccines for Medicare and other patients.

As discussed in section III.P. of this proposed rule, we are proposing regulatory updates related to the process for publication of the Code List for Certain Designated Health Services (the Code List). Specifically, we would update the Code List each calendar quarter. We would provide public notification on the CMS website in advance of each Code List update, followed by a 30-day public comment period. We would provide information on the CMS website regarding the process for submitting public comments through *www.regulations.gov*, and address all public comments on the Code List on the CMS website. In addition, instead of publishing in the PFS final rule, we would publish the Code List solely on the CMS website. Finally, we would revise the definition of ''List of CPT/HCPCS Codes'' at § 411.351 by updating the URL that indicates where the Code List is published on the CMS website. We believe that these proposals would make available the most recent updates in a timelier manner and allow easier access to the most up-to-date Code List.

15. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA–PD Plan (section 2003 of the SUPPORT Act) In addition to the cost reflected in the Collection of Information section of this proposed rule, we expect that there would be an additional burden for CMS to award and work with a CMS contractor to develop a process for reviewing the PDE data to assess prescriber compliance with the regulatory provision and review and process prescriber attestations. Based on similar contracts, and conversations with the industry, we have estimated the costs of (A) development of operational strategy for the new program, (B) reviewing PDE data, and (C) prescriber case work. We solicit stakeholder feedback on this estimate and all our assumptions.

(A) *Development of policy:* We estimate that it would take our contractor a week of work, 40 hours, to develop the strategy for how the contractor will process the prescriber attestations. We estimate that it would an operations manager and compliance officer working together at a combined hourly wage of $193.60/hr ($120.90/hr + $72.70/hr) would need a full 40-hour work week to operationalize this aspect of it. Therefore, the aggregate cost would be $7,744 (40 hr * $193.60/hr).

(B) Since systems already exist to collect the appropriate PDE data, our contractor would only have to review the data for compliance with the EPCS mandate. We therefore estimate that it would take 2 computer systems analyst each working at $95.22/hr, a week and a half of work, 60 hours. Therefore, the aggregate cost is $5,713.20 (60 hr * $95.22/hr).

(C) We estimate that it would take 4 administrative support workers each working at $36.82/hr, 60 hours to generate the letters and disseminate them to the appropriate prescriber,

which means that it would cost our contractor $2,209.20/year (60 hr * $36.82/hr) in administrative support costs. We estimate that it would be the full-time job of a customer service representative working at $37.02/hr to field prescriber inquiries about the disseminated letters. Thus, we expect that our contractor will spend $77,001.60 ($37.02/hr * 40 * 52) on the salary of the customer service representative for this task.

The aggregate impact for our contractor is 200 hours at a cost of $92,668. We seek comment on the accuracy of this burden estimate and on any measures that CMS can take to decrease the impact of this provision, while maintaining its utility and implementing the statutory mandate

16. Open Payments

a. Payment Context Field for Teaching Hospitals

This proposal is for a mandatory freeform text context field. We have created this proposal at the request of stakeholders, particularly after conversations with teaching hospitals. The teaching hospitals confirmed that the majority of their disputes arise because of a lack of information within the record and an inability to attribute it to the correct area within their large organization, not the inaccuracy of the record itself. The benefit of this field is to give better context to the records attributed to teaching hospitals and thereby reduce the number of disputes. For this reason, we also believe it will also increase goodwill between the program's stakeholders. The cost is that reporting entities will need to collect an additional piece of information, which will increase burden. We do not believe this burden will be great because compared to physician covered recipient payments, the number of teaching hospital payments is much lower. In addition, we have given flexibility to this field so that the reporting entity can choose which piece of information is most appropriate and can be something that they already collect, such as a check number or name of the department in the hospital.

b. Optional Annual Recertification

The optional annual recertification is at the request of reporting entities and will increase the availability of communication to CMS. The burden associated with this action is low because it will be a low-effort process only completed by the entities who choose to do so.

c. Defining a Physician-Owned Distributorship

Since the program began in 2013, we have heard feedback that physician-owned distributorship (PODs) should be better represented in the data because the conflict of interest potentially created by PODs is at the heart of the program. We created this new definition due to the lack of an existing definition of a POD that would be appropriate for the program's needs. Though this is a new definition, it will only be a subset of the existing definitions of applicable manufacturer and applicable group purchasing organization. ''Applicable manufacturer—POD'' and ''Group purchasing organization—POD'' are already ''business type'' choices when registering in the Open Payments system. Therefore, this definition will not alter existing regulations beyond requiring PODs to identify themselves as such.

d. Disallowing Record Deletion Without Reason

We believe there is not currently language to prevent an applicable manufacturer or applicable group purchasing organization from submitting and attesting to records, then deleting the records to prevent publication. This action would be contrary to the spirit of transparency of the program. To help ensure compliance with this requirement, we are also adding a new field that will allow entities to communicate the reason for the deletion to CMS. Since the entities will have attested to the accuracy and completeness of these records, we believe it is appropriate to confirm the reason for the deletion. We have not perceived the behavior of inappropriate deletions within the data and do not believe it will increase burden beyond the additional field when deleting a record. We are preemptively closing a potential loophole.

e. Disallow Publication Delays of General Payments

The statute requires that delays are ''made pursuant to product research or development agreements and clinical investigations'' (1128G(c)(1)(E) of the Act). A small number of general payments are delayed annually, which we are unable to verify meet this requirement. Research payments contain the appropriate fields to ensure that the statutory provisions are being met. We do not believe that it will be a burden for the small number of general payments to either be reported as research payments or not delayed.

f. Short-Term Loans

Short-term loans are not required to be reported, but they must be shorter than 91 days to meet the exception. This proposal does not create burden because it only clarifies that those 90 days must be the cumulative total for a year, which is already outlined in subregulatory guidance. We do not anticipate that this will change reporting behavior but want to explain the exception more clearly within the text of the final rule.

g. Remove General Ownership Records

Ownership records have special rules for reporting outlined in the statute (section 1128G(a)(2) of the Act), which are not included in the format for general records. However, there is currently a general record for reporting ownership and investment interest (Nature of Payment = 11). We anticipate a small burden for the approximately 92 reporting entities who have previously used the general nature of payment category in order to fill out the different fields in the ownership record. This burden will allow the records to meet statutory mandates.

h. Updated Contact Information

Open Payments conducts regular compliance-related outreaches to reporting entities when it encounters data that may not meet program requirements. We have found that the two contacts provided by applicable manufacturers and group purchasing organizations often become obsolete, especially if a company has not updated its contact information during the recertification process. It is crucial for the integrity of the data that we have the ability to contact entities in the case of irregularities. Additionally, we believe that ensuring informal communications from CMS will reduce burden since it may prevent more formal compliance actions if the entity is unresponsive due to outdated contact information. However, we do not believe this is an issue for the majority of reporting entities, nor do we believe that keeping the contact information updated will create a large burden.

17. Updates to the Quality Payment Program

In section IV.A. of this proposed rule, we included our proposed policies for the Quality Payment Program. In this section, we first present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In the following sections, we estimate the overall and incremental impacts to the total MIPS eligible population and the payment impacts by practice size for the 2022

MIPS performance period based on various proposed policies, including to modify MIPS eligibility, the MIPS final score and the performance threshold and additional performance threshold as discussed in sections IV.A.3.a.(1) and IV.A.3.f. of this proposed rule.

This RIA uses the 2019 MIPS performance period submissions that were used for the CY 2021 PFS final rule RIA (85 FR 85011 through 85023). The submissions for the 2020 MIPS performance period were not available in time to incorporate into this model and to assess whether the data for 2020 can be used to effectively predict future performance. For the 2020 performance year, we applied the MIPS automatic extreme and uncontrollable circumstances policy to all individual MIPS eligible clinicians and allowed for extreme and uncontrollable applications due to the COVID–19 Public Health Emergency (PHE) (*https://qpp.cms.gov/resources/covid19?py=2020*). Due to these extreme and uncontrollable circumstances policy, not all clinicians or groups may have submitted performance category data for the 2020 MIPS performance period. We will evaluate for the final rule whether it is appropriate to use the 2020 performance period data and whether adjustments would need to be made if CY 2020 performance category submissions data are used.

We ran two RIA models: A baseline and proposed policies RIA model. The aim of the baseline model is to reflect the CY 2022 performance period/2024 MIPS payment year if this proposed rule did not take effect, and therefore, reflects previously finalized policies for the CY 2022 performance period/CY 2024 MIPS payment year. Select examples of the baseline policies scheduled to start in the CY 2022 MIPS performance period/2024 MIPS payment year include the removal of the Web Interface as a collection type and the change in the performance category weights. Our baseline model used the performance threshold and additional performance threshold of the CY 2021 MIPS performance period/2023 MIPS payment year since those values were not previously defined for the CY 2022 MIPS performance period/2024 MIPS payment year. The aim of the proposed policies model is to estimate the incremental effect of the proposed policies for the CY 2022 performance period/CY 2024 MIPS payment year on MIPS eligibility, MIPS final scores, and payment adjustments. Select examples of the proposed policies include, the inclusion of new MIPS eligible clinician types, the inclusion of the Web Interface as a collection type, the change in performance threshold and additional performance threshold, and the new complex patient bonus. Refer to section VII.F.17.d.(2) of this proposed rule for the detailed methods on how we integrated the policies into the baseline and proposed policies models.

a. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

For payment years from 2019 through 2024, through the Medicare Option, eligible clinicians who have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs will be QPs in the applicable QP performance period for a year. These QPs will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs.

Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs, but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the update to the PFS CF for services that are furnished by clinicians who achieve QP status for a year is 0.75 percent, while the update to the PFS CF for services that are furnished by clinicians who do not achieve QP status for a year is 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact analysis covers only the 2024 MIPS payment year of the Quality Payment Program.

Overall, we estimate that for the 2022 QP Performance Period between 225,000 and 290,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment in Payment Year 2024 based on 5 percent of their Part B paid amounts for covered professional services in the preceding year. These paid amounts for QPs are estimated to be between approximately $12,000 million and $15,000 million in total for the 2022 performance year. The analysis for this proposed rule used the 2020 third snapshot participation file. We based APM Incentive Payment Amounts on paid amounts with service dates of January 1, through September 30, 2020. We multiplied the calculated amounts by 1.5 to approximate payment amounts for the full calendar year. We estimate that the total lump sum APM Incentive Payments will be approximately $600–750 million for the 2024 Quality Payment Program payment year.

In section VII.F.17.a. of this proposed rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2022 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2022 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. We note that the Kidney Care Choices Model and the Radiation Oncology model have been included in our analysis as we anticipate that the model will be Advanced APMs in 2022. The following APMs are expected to be Advanced APMs for the 2022 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Global and Professional Direct Contracting Model;

- Kidney Care Choices Model (Kidney Care First; Professional Option and Global Option);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Basic Track Level E, and the ENHANCED Track);
- Oncology Care Model (Two-Sided Risk Arrangements);
- Primary Care First (PCF) Model;
- Radiation Oncology model; and,
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (see 81 FR 77444 through 77445 for information on the APM Participant Lists and QP determinations) on the 2020 third snapshot participation file to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2022 QP Performance Period. We examined the extent to which Advanced APM participants would meet the QP Thresholds of having at least 50 percent of their Part B covered professional services or at least 35 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

b. Impact for the CY 2021 MIPS Performance Period/2023 MIPS Payment Year

In section IV.A.3.e.(2)(a)(ii) of this proposed rule, we proposed to double the complex patient bonus, and to increase its cap to 10 points. We expect this proposed policy to result in the median bonus to increase by 3 points, thus increasing MIPS final scores at the median by 3 points. We do not know the effects of the PHE for COVID–19 and its effect on MIPS performance in 2021, so we did not recreate the analysis and payment distributions with the updated bonus for the 2021 MIPS performance period (85 FR 85012 through 85019). Directionally, the increase in complex patient bonus points will result in smaller payment adjustments for three reasons. First, the resulting increase in final scores will reduce the budget neutral pool. Second, the increase in complex patient bonus points will increase the number of clinicians with scores above the performance threshold or additional performance threshold, meaning more clinicians will share in the budget neutral pool and additional $500 million for exceptional performance and potentially lowering the scaling factor that is applied to the MIPS payment adjustment and additional payment adjustment. Third, the average scores of those receiving a positive or additional adjustment will be higher, which means the adjustment rates for clinicians that have scores above the performance threshold or additional performance threshold will be lower.

c. Estimated Number of Clinicians Eligible for MIPS Eligibility for the 2022 MIPS Performance Period/2024 MIPS Payment Year

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the 2022 MIPS performance period and the effect of the proposed policies in this proposed rule, we ran two models as described in section VII.F.17.: A baseline model and proposed policies model.

For the baseline and proposed policies models, we used the same eligibility files and approach as described in the CY 2021 PFS final rule (85 FR 85013), which resulted in the inclusion of 1.6 million clinicians who had PFS claims from October 1, 2018 to September 30, 2019 as well as additional clinicians associated with a group who had at least one PFS claim from October 1, 2019 through December 31, 2019. We used the same exclusion criteria to exclude clinicians from our MIPS eligibility assessment as described in the CY 2021 PFS final rule RIA (85 FR 85013), with the following model updates:

(1) In both the baseline and proposed policies models, we excluded practitioners in Next Generation ACOs because the Next Generation ACO model ends in the CY 2021 MIPS performance period.

(2) In both the baseline and proposed policies models, to determine which clinicians in the initial population of 1.6 million should be excluded as QPs, we used Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period. We elected to use this data source because the APM participant list for the 2019 final snapshot can reliably be used for RIA projections. From this data, we calculated the QP and Partial QP determinations as described in section of IV.A.4.c.(1)(b) of this proposed rule for the 2022 QP performance period for both models.

(3) In the proposed policies model, we included in our estimated MIPS eligible population for the CY 2022 performance period/2024 payment year clinical social workers and certified nurse-midwives as proposed in section IV.A.3.a.(1) of this proposed rule.

(4) In the proposed policies model, we are integrating the proposal that starting with the CY2022 MIPS performance period/2024 MIPS payment year, small practices, excluding virtual groups, must submit data as a group in any performance category to indicate that they wish to be scored as a group for Medicare Part B claims. This affects eligibility because previously a single Medicare Part B claims submission, without any other submission, started a group score. Once a group score is created, a clinician who was individually excluded from MIPS for being under the low-volume threshold, may now be eligible if the group exceeds the low-volume threshold. This proposed policy is described at section IV.A.3.a. of this rule.

(b) Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (TIN/NPI) or group (TIN) levels based on how data are submitted or at the APM Entity level if the clinician is part of an APM Entity in a MIPS APM (hereafter, a MIPS APM Entity) that elects to submit to MIPS. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment.

For the proposed policies model, we describe below the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians. We present in section VII.F.17.c.(1)(c) the incremental impact of the proposed policies from the baseline model for the CY 2022 performance period/2024 payment year on the MIPS eligible clinician population and their associated PFS allowed charges. We applied the same assumptions presented in the CY 2021 PFS final rule RIA to apply the low-volume threshold and to understand whether clinicians participate as a group, virtual group, APM entity, or as individuals (85 FR 85013 through 85016), except for three modifications. We assumed only individuals or APM TINs that exceeded the low-volume threshold would receive an APM Performance Pathway (APP) score consistent with the policy as finalized in the CY 2021 PFS final rule (85 FR

84897).[263] We assumed APM TINs that qualified for opt-in and submitted data as a TIN would also be eligible. Finally, we did not consider clinicians in groups as MIPS eligible clinicians and start a group score for clinicians in small practices with only Medicare Part B claims submissions to reflect the proposed policy at section IV.A.3.a. of this rule.

For the proposed policies model, we estimate approximately 212,000 clinicians[264] will be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. These clinicians may ultimately choose to participate in MIPS as an individual, group, virtual group or APM entity. We identify these clinicians as having ''required eligibility'' in Table 129. We estimate approximately 595,000 additional MIPS eligible clinicians will be eligible because they belong to an APM entity, group or virtual group that meets the low-volume threshold and submits to MIPS. These clinicians are identified as having ''group eligibility'' in Table 129. Finally, we estimate about 3,000 clinicians would be eligible through ''opt-in eligibility'' through the ''opt-in'' policy for a total MIPS eligible clinician population of approximately 810,000. This leads to an associated $67 billion allowed PFS charges estimated to be included in the 2022 performance period/2024 payment year.

[263] Under the proposed policy, APM TINs must submit data, but as that was not a requirement for 2019 Shared Saving Program participants, we assumed all TINs that exceed the low-volume threshold would submit data.

[264] The count of 212,000 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (approximately 185,000 MIPS eligible clinicians), as well as those who did not participate (approximately 27,000 MIPS eligible clinicians).

TABLE 129: Description of MIPS Eligibility Status for CY 2022 Performance Period/2024 MIPS Payment Year Using the CY 2022 PFS Proposed Rule Assumptions**

		CY 2022 PFS Proposed Rule estimates	
Eligibility Status	**Predicted Participation Status in MIPS Among Clinicians***	**Number of Clinicians**	**PFS allowed charges ($ in mil)*****
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	184,773	$ 45,007
	Do not participate in MIPS	27,015	$6,313
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	594,578	$15,195
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	3,259	$ 77
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**809,625 ***	**$ 66,592**
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	411,872	$ 10,529
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	100,501	$ 565
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	303,873	$ 14,951
Total Number of Clinicians Not MIPS Eligible		816,246	$ 26,045
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,871	$ 92,638

* Estimated MIPS Eligible Population

** This table does not include clinicians impacted by the automatic extreme and uncontrollable policy. (approximately 6,000 clinicians and $527 million in PFS allowed charges). It also excludes CPC+, NextGen and submitters with one or more categories identified as being suppressed as a result of bad data.

*** Allowed charges estimated using 2019 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

Furthermore, we estimate there will be approximately 412,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate or they elect to opt-in. We describe this group as ''Potentially MIPS eligible'' in Table 129. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group, or clinicians in a group that does not submit are eligible to opt-into MIPS individually and choose to do so. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1.2 million clinicians.

Finally, we estimate approximately 101,000 clinicians would not be MIPS eligible because they and their group are below the low-volume threshold on all three criteria and another approximately 304,000 would not be MIPS eligible because they are categorically excluded regardless of volume or submission activity.

Eligibility among many clinicians is contingent on submission to MIPS as a group, virtual group or election to opt-in, therefore we will not know the number of MIPS eligible clinicians who submit until the submission period for the 2022 MIPS performance period is closed. For this proposed policies model analysis, we use the estimated population of 809,625 MIPS eligible clinicians described above.

(c) Estimated Impact of the Proposed Policies on MIPS Eligibility and PFS Allowed Charges

We illustrate in Table 130 how the proposed policy to add clinical social workers and certified nurse-midwives as MIPS eligible clinician types as proposed in section IV.A.3.a.(1) of this proposed rule affects the estimated number of MIPS eligible clinicians. The first row presents the estimates from the RIA baseline model with the number of individuals that would be MIPS eligible clinicians for the 2022 MIPS performance period/2024 MIPS payment year if this proposed rule did not take effect. The second row presents estimates from the RIA proposed policies model with the incremental impact of adding the two new MIPS eligible clinician types on the number of MIPS eligible clinicians for the CY 2022 MIPS performance period/2024 MIPS payment year. As shown in Table 130, the proposed policy to add clinical social workers and certified nurse-midwives as MIPS eligible clinician types leads to a small increase in the number of MIPS eligible clinicians (1.1 percent increase) and a minimal increase in the PFS allowed charges (0.1 percent increase) for the CY 2022 performance period/2024 payment year.

TABLE 130: Effect of Eligibility Changes on the Expected Number of Clinicians and the Allowed Paid Amount in the CY 2022 Performance Period/2024 Payment Year

Policy changes	Estimated cumulative effect of policy change on number of clinicians	Estimated number of clinicians impacted by policy change	% Change /from Baseline in number of MIPS eligible clinicians	Estimated Cumulative PFS Allowed Charges (mil)	% Change in PFS Allowed Charges from Baseline
Baseline policies model: If the CY 2022 proposed rule did not exist.	801,013	N/A	N/A	66,503	N/A
Proposed policies model: Proposed policies for CY 2022 MIPS performance period/2024 payment year.	809,625	8,612	1.1%	66,592	0.1%

d. Estimated Impacts on Payments to MIPS Eligible Clinicians for the CY 2022 Performance Period/2024 Payment Year

(1) Summary of Approach

In sections IV.A.3.d., IV.A.3.e. and IV.A.3.f. of this proposed rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VII.F.17.d. of this RIA as we describe our methodology to estimate MIPS payments for the CY 2022 performance period/2024 payment year. We then present the impact of the overall proposed policies on the CY 2022 performance period/2024 payment year and then compare select metrics to the baseline model, which only incorporates previously finalized policies for the CY 2022 performance period/2024 payment year. By comparing the baseline model to the proposed policies model, we are able to estimate the incremental impact of the proposed policies for the CY 2022 performance period/2024 payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, and MIPS eligible clinicians can participate as an individual, group, virtual group, or APM Entity in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VII.F.17. of this proposed rule, we generally used the most recently available submissions data from the Quality Payment Program which is data submitted for the 2019 MIPS performance period. For the cost performance category, we used the same data as the CY 2020 PFS final rule (84 FR 63169).

The estimated payment impacts presented in this proposed rule are averages by practice size weighted by Medicare utilization. The payment impact for a MIPS eligible clinician will vary from the average and would depend on the measure submissions, scores and their performance. The average percentage change in total revenues that clinicians earn would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare FQHC PPS, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2022 performance period/2024 MIPS payment year for this proposed rule, we generally used 2019 MIPS performance period data for both the baseline and proposed policies models. Our baseline and proposed policies scoring models included the 801,013 and 809,625 estimated MIPS eligible

clinicians, respectively, as described in section VII.F.17.c.(1) of this RIA.

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the 2019 MIPS performance period submissions data, including data submitted for the quality, improvement activities, and Promoting Interoperability performance categories. We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, testing data for the revised total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) clinician measures which were finalized in the CY 2020 PFS final rule (84 FR 62969 through 62977), testing data for the new episode cost measures, administrative claims data for the new quality performance category measures, and other data sets.[265] We calculated a hypothetical final score for the 2022 MIPS performance period/2024 MIPS payment year for the baseline and proposed policies scoring models for each MIPS eligible clinician using score estimates for quality, cost, Promoting Interoperability, and improvement activities performance categories, where each are described in detail in the following subsections.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a methodology like the one described in the CY 2021 PFS final rule (85 FR 85016 through 85017) for baseline and proposed policies RIA models for the CY 2022 MIPS performance period/2024 payment year.

For the baseline policies RIA model, which does not reflect the proposed policies for CY 2022 MIPS performance period/2024 payment year, we made the following modifications to reflect the previously finalized policies for the CY 2022 performance period/2024 payment year for the quality performance category:

(1) As previously finalized in the CY 2021 PFS final rule, we removed the Web Interface as a collection type in MIPS and through the APP for the CY 2022 performance period/2024 MIPS payment year (85 FR 84870 and 85 FR 84843). Although the Web Interface is proposed to be reinstated for groups for the CY 2022 MIPS performance period/2024 MIPS payment year and ACOs for CY 2022 MIPS performance period/2024 MIPS payment year and CY 2023 MIPS performance period/2025 MIPS payment year as discussed in sections IV.A.3.d.(1)(d) and IV.A.3.c.(2)(a), respectively, the baseline model is attempting to capture the CY 2022 MIPS performance period/2024 MIPS payment year as if this proposal did not exist. Therefore, the baseline model does not incorporate the Web Interface as a collection type for groups and ACOs.

To estimate a quality performance category score for clinicians in groups who previously used the Web Interface as a collection type in 2019, we assumed these groups would use the other two other collection types (MIPS CQMs and eCQMs) available in the 2022 MIPS performance period/2024 MIPS payment year. We then applied the same methodology described in the CY 2021 PFS Proposed Rule when the removal of Web Interface as a collection type was previously proposed (85 FR 50387 through 50388) using 2019 MIPS submissions data. To estimate a quality performance category score for ACOs, we used the same methodology described in the CY 2021 PFS proposed rule when the Web Interface was not included in the APP (85 FR 50388).

(2) We used the published 2021 MIPS historical quality benchmarks file to identify measures subject to the topped out scoring cap that was finalized (82 FR 53721 through 53727).[266]

For the proposed policies model, we made the following modifications to the baseline model to reflect the newly proposed policies for the 2022 MIPS performance period/2024 MIPS payment year for the quality performance category:

(1) As discussed in section IV.A.3.d.(1)(e) of this proposed rule, we propose for this proposed rule two new administrative claims measures for those for whom it is applicable: (1) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System; and (2) Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions. To implement this policy in our proposed policies RIA model for the 2022 MIPS performance period/2024 MIPS payment year, we used testing data for these new administrative claims measures.

(2) As discussed in section IV.A.3.e.(1)(c) of this proposed rule, we proposed to use performance period benchmarks for the CY 2022 performance period in accordance with § 414.1380(b)(1)(ii) as opposed to a historical benchmark. Therefore, we used 2019 MIPS performance period benchmarks calculated from the CY 2019 MIPS submissions data because the performance data for this analysis came primarily from the 2019 MIPS performance period.

(3) As discussed in section IV.A.3.e.(1)(c)(iii)(A) of this proposed rule, we proposed to remove the 3-point floor for each measure that can be reliably scored against the benchmark and score the measure from 1 to 10 points. As described in section IV.A.3.e.(1)(c)(iii)(B) of this proposed rule, we also proposed to make the following changes: (1) Remove the special scoring policy of scoring 3 points for class 2 measures, except for clinicians in small practices; (2) introduce a 5-point floor for new measures for their first two performance periods that meet data completeness and can be reliably scored against a benchmark (class 4a measures); and (3) introduce 5 points for new measures in their first two performance periods that meet data completeness, but cannot be reliably scored against a benchmark because they lack a benchmark or do not meet case minimum in the program (class 4b measures). We incorporated these scoring changes into our proposed policies model. Because we are using 2019 MIPS performance period data, we assume that measures new to the 2018 and 2019 MIPS performance periods could qualify as class 4 measures.

(4) As discussed in sections IV.A.3.e.(1)(c)(vi) and IV.A.3.e.(1)(c)(vii) of this proposed rule, we also propose to end measure bonus points for reporting high priority measures and for submitting with end-to-end electronic reporting beginning in the 2022 MIPS performance period. We incorporated these scoring changes into our proposed rule model for all MIPS collection types.

(5) As discussed in section IV.A.3.d.(1)(d), we are proposing to extend Web Interface measures for the CY 2022 performance period/2024 MIPS payment year for groups and virtual groups using the existing 10 CMS Web Interface measures. To estimate the impact of this proposed policy, we used the same methodology described in the CY 2021 PFS final rule (85 FR 85016 through 85017) using 2019 MIPS submissions data.

(6) Finally, we are also proposing to extend the CMS Web Interface as a means of reporting quality under the APM Performance Pathway for Shared Savings Program ACOs for the CY 2022 and CY 2023 MIPS performance periods and 2024 and 2025 MIPS payment years as described in section IV.A.3.c.(2)(a) of

[265] Data submitted to MIPS for the 2018 MIPS performance period data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

[266] Data downloaded on April 9 2021 from *https://qpp.cms.gov/resources/resource-library.*

this proposed rule. Under the proposal, for the CY 2022 and CY 2023 MIPS performance periods and 2024 and 2025 MIPS payment years, Web Interface reporting would work in the same manner as for performance year 2021, where ACOs would have the option of reporting either the CMS Web Interface, the APP eCQM/MIPS CQM measure set, or both. To estimate the impact of this proposed policy, we used the same methodology described in the CY 2021 PFS final rule RIA (85 FR 85016 through 85017) when Web Interface was retained for the APP.

(b) Methodology To Estimate the Cost Performance Category Score

We estimated the cost performance category score using a similar methodology described in the CY 2020 PFS final rule (84 FR 63169) with the modifications to the baseline and the proposed policies RIA model described in this section.

In the baseline policies RIA model, we refined our methodology for developing benchmarks to better reflect the previously finalized policy in CY 2017 Quality Payment Program final rule (81 FR 77308 through 77309). We did not estimate cost improvement scoring that starts in the 2022 MIPS performance period/2024 MIPS payment year as previously finalized at § 414.1380(a)(1)(ii) and in the CY 2019 PFS final rule (83 FR 58956) since we did not have sufficient data to conduct improvement scoring, which requires 2 years of cost data to model.

In the proposed policies RIA model, we modified the baseline model to incorporate the proposal to add five new episode-based cost performance category measures in the CY 2022 MIPS performance period/2024 payment year as described in section IV.A.3.d.(2) of this proposed rule, by using claims data from January 1, 2019 to December 31, 2019. Cost measures were scored if the clinicians or groups met or exceeded the case volume: 10 Episodes for Melanoma Resection to align with the reporting case minimum for procedural cost measures currently in use in MIPS, 20 episodes for Sepsis to align with the reporting case minimum for acute inpatient condition cost measures currently in use in MIPS, 20 episodes for Diabetes and Asthma/COPD as used in field testing for these chronic measures, and 20 episodes for Colon Resection. These newly proposed cost episode-based measures were calculated for both the TIN/NPI and the TIN.

(c) Methodology To Estimate the Facility-Based Measurement Scoring

For the baseline model, we estimated the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763) and the methodology described in the CY 2020 PFS final rule (84 FR 63169). For the proposed policies model, we used the methodology proposed for the CY 2022 MIPS performance period/2024 MIPS payment year as discussed in section IV.A.3.e.(2)(b)(v)(B) of this proposed rule. We propose at § 414.1380(e)(vi) that beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, the MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology unless a clinician or group receives a higher MIPS final score through another MIPS submission. Therefore, if a MIPS eligible clinician or a group is eligible for facility-based measurement, but they participate in MIPS as an individual or group, we used the higher final score between the facility-based scoring and MIPS submission-based scoring.

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

For the baseline RIA model, we used the CY 2019 MIPS Promoting Interoperability performance period data submissions data to estimate CY 2022 MIPS performance for the Promoting Interoperability performance category. We made the following two modifications to the 2019 performance period scoring to reflect the previously finalized policy changes between the CY 2019 and CY 2021 performance periods: (1) We doubled the bonus points for clinicians who submitted the PDMP measure as described in section IV.A.3.d.(4)(c)(i) of this proposed rule; and (2) we did not incorporate the Verify Opioid Treatment Agreement measure data, a measure that was finalized in the CY 2019 performance period (83 FR 59807) but removed in the CY 2020 performance period (84 FR 62994). We retained the PDMP bonus for the baseline model for continuity between the CY 2021 and 2022 performance periods and for consistency since bonuses for the quality performance category were retained for the baseline as well. Because we lacked data on who would adopt the finalized Health Information Exchange bi-directional exchange measure for the CY 2021 performance period and how these clinicians would score, we only used past reporting on the existing Health Information Exchange Objective measures to estimate CY 2022 Promoting Interoperability performance.

For the proposed rule model, we considered the following policy proposals as potential modifications to the baseline RIA model:

(1) In section IV.A.3.d.(4)(c)(i) of this proposed rule, we proposed for the PDMP measure to remain optional and at 10 points. Modifications were not made to reflect this proposed policy in the proposed policies model since the baseline model already incorporated this policy.

(2) In section IV.A.3.d.(4)(c)(iii) of this rule, we proposed to require two of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the CY 2022 performance period: Immunization Registry Reporting; and Electronic Case Reporting. Because we lacked data, we did not integrate this requirement into our proposed rule model.

(3) In section IV.A.3.d.(4)(h)(i) of this rule, we proposed to automatically reweight the Promoting Interoperability performance category to another performance category and assigned a weight of zero only in the event a small practice did not submit any data for any of the measures specified for the Promoting Interoperability performance category. This policy was implemented in the proposed policies model.

(4) In section IV.A.3.d.(4)(h)(ii) of this proposed rule, we proposed to reweight the Promoting Interoperability performance category for clinical social workers. This policy was implemented in the proposed policies model.

(5) In section IV.A.3.d.(4)(d) of this proposed rule, we proposed the additional requirement that eligible clinicians must attest to conducting an annual assessment of the High Priority Guides of the SAFER Guides beginning with the 2022 MIPS performance period. This policy was not implemented in the proposed policies model as it does not affect eligibility or payment. We included this policy in our burden calculations in section V.B.8.g.(3) of this rule.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline model, we modeled the improvement activities performance category score based on CY 2019 MIPS performance period data and APM participation identified in section VII.F.17.c.(1) of this proposed rule. For clinicians and groups not participating in a MIPS APM, we used the CY 2019 submissions improvement activities

score. We did not model the policy finalized in the CY 2020 performance period (84 FR 62980) to require a minimum threshold of 50 percent of clinicians in a group to complete an improvement activity for the group to receive credit since we did not have data to determine the proportion of clinicians in a group that completed the improvement activity. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section VII.F.17.c.(1) of this proposed rule, we assigned an improvement activity performance category score of 100 percent.

For the proposed policies model, we did not make modifications to the baseline model to reflect the proposed policies in section IV.A.3.d.(3) of this proposed rule since we did not have the data to model those changes.

(f) Methodology To Estimate the Complex Patient Bonus Points

In section IV.A.3.e.(2)(a)(iii)(B) of this proposed rule, we proposed to continue the complex patient bonus, with updates, for the CY 2022 MIPS performance period/2024 payment year. For the baseline RIA model, we used the complex patient bonus information calculated for the 2019 performance period data for the 2022 MIPS performance period/2024 payment year, as was previously done in the CY 2021 PFS final rule (85 FR 85017).

For the proposed policies RIA model, we calculated the complex patient bonus using the calculation proposed in section IV.A.3.e.(2)(a)(iii)(B)(cc) of this proposed rule for the CY 2022 performance period/2024 payment year. In section IV.A.3.e.(2)(a)(iii)(B)(aa) of this proposed rule, we propose updates to the complex patient bonus for the CY 2022 performance period/2024 payment year and future MIPS performance periods/payment years to account for social and medical complexity, while still using our current established indicators of dual proportion and HCC risk scores, respectively. Consistent with the proposed policy for the 2022 performance period, our proposed policies RIA model calculated and applied the separate risk indicator complex patient bonus components methodology with a single overall cap described in section IV.A.3.e.(2)(a)(iii)(B)(dd) of this proposed rule.

(g) Methodology To Estimate the Final Score

We did not propose any changes for how we calculated the MIPS final score. Our baseline and proposed policies RIA models assigned a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, adding the complex patient bonus, and capping at 100 points.

For the baseline policies RIA model, we applied the performance category weights and redistribution weights finalized in the CY 2021 PFS final rule (85 FR 84913 through 84916).

For the proposed policies RIA model, we proposed to modify the redistribution policy for small practices. Therefore, we applied redistribution weights proposed in section IV.A.3.e.(2)(b)(iii)(A) of this proposed rule.

For both models, after adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to section IV.A.3.e.(2)(b)(ii) of this proposed rule.

(h) Methodology to Estimate the MIPS Payment Adjustment

For the baseline and proposed policies RIA models, we applied the hierarchy as finalized in the CY 2021 PFS final rule (85 FR 84917 through 84919) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages, and additional payment adjustment for exceptional performance (as proposed under § 414.1405).

For the baseline policies model, we applied the performance threshold and additional performance thresholds finalized for the CY 2021 performance period/2023 payment year (85 FR 84923), of 60 and 85, respectively. For the proposed policies model, we used the performance threshold of 75 points as proposed in section IV.A.3.f. (2) and the additional performance threshold of 89 points as proposed in section IV.A.3.f.(3). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered professional services furnished by the MIPS eligible clinician. As discussed in the CY 2021 PFS final rule RIA (85 FR 85013), we adjusted the paid amount of non-engaged clinicians to equal their proportion of paid amount prior to the PHE for COVID–19 for the baseline and proposed policies RIA models.

(3) Impact of Payments by Practice Size

As we shift from previous MIPS transition policies by removing bonuses from the quality performance category and increasing the performance threshold and the additional performance threshold, we observe large changes between the baseline and proposed policies RIA models.

First, we observe an increase in the funds available for redistribution due to the increase in clinicians with final scores below the performance threshold. The baseline model estimates $428 million would be redistributed through budget neutrality and that $500 million would be distributed to MIPS eligible clinicians for exceptional performance. The mean and median final scores for the baseline model are 78.13 and 82.59, respectively. Our proposed policies model estimates that $587 million would be redistributed through budget neutrality. For clinicians who meet or exceed the additional performance threshold, an additional $425 million was estimated to be distributed. The mean and median final scores for the proposed policies model are 75.86 and 80.30, respectively.

In the proposed model, the estimated bonus for exceptional performance is less than the $500 million of available funding because the maximum additional payment adjustment for clinicians with exceptional performance reached 10 percent. As finalized in the 2017 QPP final rule (81 FR 77339 through 77340), we stated the maximum additional payment adjustment would be 10 percent, which is established by the statute, and that it would be multiplied by a scaling factor that cannot exceed 1.0. We reached the maximum additional payment adjustment allowed of 10 percent because the additional performance threshold is higher, and fewer clinicians performed above this higher additional performance threshold while a greater percentage of clinicians performed below the additional performance threshold. As a result, fewer clinicians were sharing the funds available through the additional bonus for exceptional performance.

Second, we observe an increase in the maximum positive payment adjustment. The baseline model estimates the maximum positive MIPS payment adjustment based on the budget neutral pool at 1.5 percent and the maximum positive MIPS additional payment adjustment for exceptional performance at 5.1 percent, for a combined maximum payment adjustment of 6.6 percent. The proposed policies model estimates the maximum MIPS positive payment adjustment based on the budget neutral pool at 4.0 percent and the maximum positive additional MIPS payment adjustment for exceptional performance bonus at 10.0 percent for a combined maximum payment adjustment of 14.0 percent.

Finally, we no longer observe large differences in performance across practice sizes due to the shift from MIPS transition policies. Table 131 shows the overall impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS for the proposed policies model. We estimate performance under the proposed policies will be similar across all practice sizes. The smallest proportion of clinicians receiving a positive or neutral payment adjustment is among clinicians in practices with 16 to 24 clinicians compared to other sized practices among those who submit data. Table 131 also shows that overall 67.5 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. In Table 132, we present the overall impact of the baseline and the proposed policies models among clinicians who submit data to assess the incremental impact of the proposed policies. The overall proportion of clinicians receiving a positive or neutral payment adjustment decreases from 91.7 percent to 67.5 percent with the implementation of the proposed policies that shift away from MIPS transition policies. Among clinicians who receive a positive payment adjustment in the baseline model and receive a negative payment adjustment in the proposed policies model, only 30 percent receive a negative payment adjustment greater than 1 percent. In addition, we no longer observe a disproportionate number of clinicians in small practices receiving a negative payment adjustment when implementing the proposed policies.

For the CY 2022 performance period/2024 payment year, we have policies targeted towards small practices including special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs, which we describe in section VII.F.17.f.(2)(e) of this proposed rule. The intention of the proposed policies is to provide a more equitable participation process and reduce the disparity in performance between clinicians in large and small practices. These findings and proposed policies reflect movement away from the transition policies implemented during the early years of MIPS and how MIPS is focusing on value rather than primarily on engagement. However, non-engagement by not submitting data to MIPS among clinicians in small practices is still a concern. Among those who we estimate would not submit data to MIPS, 85 percent are in small practices (23,056 out of 27,108 clinicians who do not submit data). We intend to continue working with stakeholders to improve engagement in MIPS among clinicians in small practices.

We want to highlight we are using 2019 MIPS performance period submissions data to simulate a 2022 MIPS performance period final score, and it is likely that there will be changes that we cannot account for at this time, including services and payments disrupted by the PHE for COVID–19 or clinicians changing behavior in response to the performance thresholds increased for the 2022 performance period/2024 payment year to avoid a negative payment adjustment. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2022 MIPS performance period/2024 payment year. This is because the PHE for COVID–19 may have resulted in fewer clinicians submitting data to MIPS or more clinicians electing to apply for the extreme and uncontrollable circumstances policies due to the PHE for COVID–19 for the 2019 MIPS performance period. Therefore, engagement levels in MIPS for the CY 2022 performance period/2024 payment year may differ from these reported estimates. We also note this participation data is generally based off participation for the 2019 performance period, which is associated with the 2019 performance period/2021 payment year and had a performance threshold of 30 points, and that participation may change for the 2022 performance period/2024 payment year when the performance threshold is 75 points.

Finally, the combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because some MIPS eligible clinicians that do not submit data to MIPS receive a non-zero score for the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS.

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TABLE 131: MIPS Estimated 2022 Performance Period/2024 Payment Year Impact on Total Estimated Paid Amount by Participation Status and Practice Size**

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount***
Among those who submit data**					
1) 1-15	107,712	64.8%	23.7%	35.2%	1.6%
2) 16-24	36,819	60.6%	18.8%	39.4%	0.7%
3) 25-99	174,803	64.7%	19.5%	35.3%	1.1%
4) 100+	463,183	69.7%	15.1%	30.3%	1.2%
Overall	**782,517**	**67.5%**	**17.4%**	**32.5%**	**1.3%**
Among those not submitting data					
1) 1-15	23,056	0.0%	0.0%	100.0%	-8.4%
2) 16-24	1,200	0.0%	0.0%	100.0%	-8.5%
3) 25-99	2,206	0.0%	0.0%	100.0%	-8.5%
4) 100+	646	0.0%	0.0%	100.0%	-8.7%
Overall	**27,108**	**0.0%**	**0.0%**	**100.0%**	**-8.4%**

NOTE: Results of this model may change significantly if more clinicians apply for the application-based extreme and uncontrollable circumstances policy exception in CY 2021 because of the PHE for COVID-19.

*Practice size is the total number of TIN/NPIs in a TIN.

** 2019 data used to estimate 2022 performance period/2024 payment year payment adjustments. Payments estimated using 2019 dollars trended to 2024.

***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.

****Includes facility-based clinicians cost and quality data are submitted through hospital programs.

TABLE 132: CY 2022 Performance Period/2024 Payment Year Impact on Total Estimated Paid Amount among Clinicians Who Submit Data by Practice Size for the Baseline and Proposed Policies Models**

Practice Size*	Number of MIPS eligible clinicians	Percent Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount***
Baseline model among clinicians who engaged with MIPS**					
1) 1-15	107,393	78.8%	38.9%	21.2%	1.2%
2) 16-24	36,447	86.3%	39.8%	13.7%	1.5%
3) 25-99	172,758	89.7%	42.5%	10.3%	1.6%
4) 100+	457,313	95.9%	43.4%	4.1%	1.5%
Overall	**773,911**	**91.7%**	**42.4%**	**8.3%**	**1.4%**
Proposed policies model among clinicians who engaged with MIPS**					
1) 1-15	107,712	64.8%	23.7%	35.2%	1.6%
2) 16-24	36,819	60.6%	18.8%	39.4%	0.7%
3) 25-99	174,803	64.7%	19.5%	35.3%	1.1%
4) 100+	463,183	69.7%	15.1%	30.3%	1.2%
Overall	**782,517**	**67.5%**	**17.4%**	**32.5%**	**1.3%**

*Practice size is the total number of TIN/NPIs in a TIN.
**2019 data used to estimate 2022 performance period payment adjustments. Payments estimated using 2019 dollars trended to 2024.
***The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.
****Includes facility-based clinicians whose cost and quality data are submitted through hospital programs.

e. Estimated Impacts on Payments to MIPS Eligible Clinicians for the 2023 MIPS Performance Period/2025 MIPS Payment Year

We are proposing for the CY 2023 MIPS Performance Period to begin transitioning to MIPS Value Pathways (MVPs) and introduce subgroup reporting in the CY 2023 MIPS performance period/2025 payment year. As described in section IV.A.3.b.(2)(d) of the proposed rule, the first step in the transition plan for MVPs and subgroup reporting is to be voluntary, where eventually MVPs and subgroups will become required. Additionally, subgroups, if applicable, will have the option to report an APP. Since MVP and subgroup reporting will only begin in the CY 2023 MIPS performance period/2025 payment year, we do not have the data to report who would select MVP and who would report through subgroup in the first year and how these clinicians will score. For this regulatory impact analysis, we assume clinicians who elect to use MVPs and subgroups for reporting to MIPS will perform similarly to how they performed through traditional MIPS because the scoring policies are similar. As discussed in section V.B.8.e.(7)(a) of this proposed rule, for the purposes of estimating burden associated with the proposal to implement MVP and subgroup reporting, we assume that 10 percent of MIPS eligible clinicians in the CY 2022 MIPS performance period/2024 payment year will report as MVP participants in the CY 2023 MIPS performance period/2025 payment year. In addition, we assume that there will be 20 subgroup reporters in the CY 2023 MIPS performance period/2025 payment year. We anticipate a per respondent reduction of 3 hours and $412 dollars per CQM/QCDR quality submission, 3 hours and $336 per eCQM quality submission, and 5 hours and $717 per claims quality submission. Overall, we estimate a net reduction in burden of $7,463,145 in the quality performance category ICRs due to the introduction of MVP and subgroup reporting in the CY 2023 MIPPS performance period/2025 payment year. We refer readers to section V.B.8.e.(7)(a)(iii) of the proposed rule for further discussion of burden associated with MVPs and subgroups.

f. Additional Impacts from Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting the payment adjustments, we are proposing several policies that have an impact on burden in the CY 2022 and CY 2023 MIPS performance periods/2024 and 2025 payment years. In section V.B.8 of this proposed rule, we outline estimates of the costs of data collection that includes both the effect of proposed policy updates and adjustments due to the use of updated data sources. For each proposal included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 133. We also provide proposed additional burden discussions that we are not able to quantify.

TABLE 133: Incremental Burden from Associated Proposed Policies

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
Total burden associated with the proposal to continue the policies and ICRs set forth in the CY 2021 PFS final rule into the CY 2022 and 2023 MIPS performance periods (as discussed in section V.B.8.p.)	1,468,547	$148,093,881
Burden change due to proposed policy to continue the CMS Web Interface measures as a collection type/submission type for CY 2022	+7,030	+$669,433
Burden change due to proposed policy to sunset the CMS Web Interface measures as a collection type/submission type for CY 2023*	0	0
Burden change due to proposed policy to continue CMS Web Interface group registration for CY 2022	+23	+2,142
Burden change due to proposed policy to continue CMS Web Interface group registration for CY 2023	0	0
Burden change due to the proposed policy to require QCDRs to submit participation plans for the CY 2022 self-nomination period., if necessary	+156	+$14,826
Burden change due to the proposed policy to require qualified registries to submit participation plans for the CY 2022 self-nomination period., if necessary	+108	+$10,322
Burden change due to the proposed revised criteria for nomination of improvement activities: proposed increase of criteria from 1 to 8 including proposed addition of 2 new criteria for nomination of improvement activities beginning with the CY 2022 Annual Call for MIPS Improvement Activities	+43	+$6,236
Burden change due to proposed automatic reweighting of the Promoting Interoperability performance category for small practices	-3,474	-$330,747
Burden change due to proposed SAFER guides attestation requirement for the Promoting Interoperability performance category for CY 2022	+861	+$81,964
Burden change due to the new ICR for capturing proposed MVP registration requirement for clinicians participating in MVPs reporting beginning with the CY 2023 MIPS performance period*	+3,230	+$307,513
Burden change due to the new ICR for capturing proposed subgroup registration requirement for clinicians choosing to participate as subgroups for reporting the MVP or the APP beginning with the CY 2023 MIPS performance period*	+10	+$952
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to MVP Quality Submissions beginning with the CY 2023 MIPS performance period*	-40,118	-$4,037,279
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to MVP Quality Submissions beginning with the CY 2023 MIPS performance period*	-47,264	-$4,801,691
Burden change for Quality Data Submission by Clinicians: eQM Collection Type ICR for capturing reduced number of quality submissions due to MVP Quality Submissions beginning with the CY 2023 MIPS performance period*	-38,926	-$3,988,122
Burden change due to new ICR for capturing the proposed	+84,336	+$8,564,735

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
reduced reporting requirements for the quality performance category of MVPs beginning with the CY 2023 MIPS performance period *		
Total change in burden due to policy for CY 2022	**+3,811**	**-+$358,556**
Total change in burden due to policy for CY 2023	**-40,982**	**- $4,166,021**
Total burden set forth in the CY 2022 PFS proposed rule for CY 2022	**1,428,537**	**$144,040,730**
Total burden set forth in the CY 2022 PFS proposed rule for CY 2023	**1,383,744**	**$139,516,153**

* The total change in burden due to this policy includes a decrease in burden due to elimination of the "Quality Data Submission: CMS Web Interface collection type" ICR beginning with the CY 2023 MIPS performance period and "Group Registration for CMS Web Interface" ICR beginning with the CY 2023 MIPS performance period as well as an increase in burden for the "Quality Data Submission: MIPS CQM and QCDR collection type" and "Quality Data Submission: eCQM collection type" ICRs beginning with the CY 2023 MIPS performance period for respondents who previously submitted via the CMS Web Interface submitting data via an alternate collection type. Burden will decrease in the "Quality Data Submission: MIPS CQM and QCDR collection type," "Quality Data Submission: eCQM collection type," and "Quality Data Submission: Claims collection type" ICRS beginning with the CY 2023 MIPS performance period due to respondents who previously submitted MIPS through those collection types submitting data with reduced Quality submission requirements as a MVP participant. Total change in burden also includes the increase in submission burden due to the introduction of the "MVP Quality Submission," "MVP registration," and "Subgroup registration" ICRs beginning with the CY 2023 MIPS performance period. See section V.B.8 of this proposed rule.

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(2) Additional Impacts to Clinicians

(a) Web Interface

As discussed in section IV.A.3.d.(1)(d) of this proposed rule, we are proposing to continue the use of the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians for the CY 2022 MIPS performance period/2024 MIPS payment year. We are also proposing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the CY 2023 MIPS performance period/2025 MIPS payment year. We refer readers to sections V.B.8.e.(8) and V.B.8.e.(10) of this proposed rule for our discussion on the estimated burden associated with the extension of the CMS Web Interface collection type in CY 2022 MIPS performance period/2024 MIPS payment year and the sunset of the CMS Web Interface collection type in the CY 2023 MIPS performance period/2025 payment year. Additionally, we assume that the impacts associated with the sunset of CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians will remain the same as our discussion in the CY 2021 PFS final rule (85 FR 85020 through 85021).

As discussed in section IV.A.3.c.(2)(a), we are proposing to extend the CMS Web Interface as a means of reporting quality under the APP for Shared Savings Program ACOs for the CY 2022 MIPS performance period/2024 payment year and the CY 2023 MIPS performance period/2025 payment year.

(b) Administrative Claims Measure

As discussed in section IV.A.3.d.(1)(e), we are proposing to add the following two new administrative claims measures beginning in the 2022 MIPS performance period and for future performance periods: (1) Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System; and (2) Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there are no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(c) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.3.d.(3)(c)(ii) of this proposed rule, we are proposing the removal of 7 previously adopted improvement activities, modification of 15 existing improvement activities, and adoption of 5 new improvement activities. We refer readers to Appendix 2 of this proposed rule for further details. We do not believe these proposed changes to the inventory will impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these proposed changes to the inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate most clinicians performing improvement activities, to comply with existing MIPS

policies, would continue to perform the same activities under the policies in this proposed rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the CY 2022 MIPS performance period.

(d) Stakeholders Nominating Improvement Activities

In section IV.A.3.d.(3)(c)(i)(B) of this rule, we are proposing: (1) To revise the required criteria for improvement activity nominations received through the Annual Call for Activities; (2) changes to the timeline for improvement activities nomination during a public health emergency (PHE); and (3) to suspend activities that become obsolete or impacted by clinical practice guideline changes from the program when this occurrence happens outside of the rulemaking process.

With regard to the proposal to clarify the timeline for an improvement activity nominated during the PHE, we believe this proposal will not affect our currently approved burden estimates since we believe that the number of nominations will not change, but it would make an activity available for reporting to clinicians in the same performance year it was intended to be implemented. In section IV.A.3.d.(3)(c)(i)(B)(aa) of this rule, we are proposing that in order to implement a new improvement activity for a PHE during the same year as the nomination, the nomination would need to be received no later than January 5th of the nomination year to be included in a rule for notice-and-comment rulemaking during that fiscal or calendar year, a necessary precursor to implementation if it were to be finalized. As described in section V.B.8.j of this rule, we expect additional nominations may be received as a result of this proposal, but we do not have any data with which to estimate what the additional number may be. As a result, we are not making any proposed revisions to our currently approved burden estimate.

Regarding the proposal to suspend activities that become obsolete or impacted by clinical practice guideline changes from the program when this occurrence happens outside of the rulemaking process, we do not anticipate additional burden for stakeholders because of the proposal described above as the proposed policy does not change requirements for the nomination of improvement activities.

As described in section IV.A.3.d.(3)(c)(i)(B) of this rule, due to the proposals to add two new criteria and to increase the number of criteria stakeholders are required to meet when submitting an activity proposal from a minimum of 1 to all 8 criteria, which includes the two new proposed criteria, we propose to revise our estimated annual information collection burden for nomination of improvement activities to 136 hours (31 nominations × 4.4 hr/nomination) at a cost of $20,355 (31 × [(2.8 hr × $114.24/hr) + (1.6 hr × $210.44/hr)]).

(e) Impact on Small Practices

As described in section VII.F.17.d.(3) of this proposed rule RIA, we found 85 percent of clinicians who did not submit data to MIPS were in small practices. However, the estimated number of MIPS eligible clinicians who do not submit data, including those in small practices, may be smaller in the CY 2022 performance period/2024 payment year since more clinicians may choose to submit data after the PHE for COVID–19. CMS is committed to identifying flexibilities and options to help clinicians in small practices participate meaningfully and successfully in MIPS. Specifically, CMS made several proposals to support clinicians in small practices once they engage with MIPS in the quality, improvement activities and Promoting Interoperability performance categories for the CY 2022 performance period/2024 payment year. Based on our RIA model findings described in section VII.F.17.d.(3) of this proposed rule, the proposed policies for the CY 2022 performance period/2024 payment year led to clinicians in small practices no longer disproportionately receiving negative payment adjustments compared to clinicians in larger sized practices. Therefore, the combination of the special scoring policies for clinicians in small practices is expected to positively affect this group of clinicians and will hopefully encourage and improve future engagement in MIPS among clinicians in small practices.

(f) Impact on Third Party Intermediaries

In section IV.A.3.h. of this rule, we are proposing multiple changes to the third-party intermediary regulations at § 414.1400. Specifically, we are proposing: (1) Reorganization and consolidation of § 414.1400 generally; (2) expanding the general participation requirements of third-party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all participants in MIPS; (3) beginning with the CY 2023 MIPS performance period/2025 payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. Health IT vendors must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data; (4) require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 MIPS performance period/2025 payment year; (5) require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 MIPS performance period/2019 payment year) through the 2020 MIPS performance period/2022 payment year, to submit a participation plan as part of their self-nomination for CY 2023; (6) beginning with the 2024 MIPS performance period/2026 payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval; (7) beginning with the CY 2023 MIPS performance period/2025 payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency; and (8) add a rejection criterion to state that a QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period. Additionally, to provide further clarification of our current policy (84 FR 63070 through 63073), we are proposing to state, if a QCDR measure owner is not an approved active QCDR for a given self-nomination period, that QCDR measure will not be available for use. The inactive QCDR measure owner has the option to transfer ownership of the QCDR measure to an active QCDR or agree upon terms set forth with the active QCDR allowing co-ownership of the QCDR measure.

With regard to the reorganization and consolidation of § 414.1400 generally, we do not anticipate this to require any additional effort for affected entities as the proposal is to allow CMS to reorganize the existing information.

For the requirements related to expanding the general participation requirements of third-party intermediaries to third party intermediaries reporting to MIPS on behalf of APM Entities in order to align reporting requirements for all

participants in MIPS, we do not propose to revise our burden estimates as this requirement is not different from how third-party intermediaries currently submit data for the quality, improvement activities and Promoting Interoperability performance categories in MIPS on behalf of individual eligible clinicians and groups.

As previously discussed in section IV.A.3.h.(2)(b)(ii) of this rule, we are proposing to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the CY 2023 MIPS performance period/2025 payment year. During the MVP Town Hall held in January 2021 (85 FR 74729), we heard from third-party intermediaries that they are confident that they can make the necessary updates to allow for subgroup reporting, if they have enough time. A few vendors suggested that we add subgroup reporting to the existing CEHRT requirements. Given our proposal described in section IV.A.3.b.(2)(d) of this rule to delay the implementation of subgroup reporting option to the CY 2023 MIPS performance period/2025 payment year, we assume that the proposed delay would give these entities adequate time to make the necessary updates. We assume that there will be no additional burden that third-party intermediaries will incur to implement the subgroup reporting option. We anticipate that there may be administrative burden associated with changes in workflows to their existing systems for submission of subgroup data for the CY 2023 MIPS performance period/2025 payment year. However, given that each of these entities and their information technology systems are unique, we are unable to quantify the burden for these entities to capture and submit data on behalf of clinicians who may choose to participate as subgroups.

We do not anticipate a significant impact to QCDRs and qualified registries resulting from the finalized proposal to require QCDRs and qualified registries to conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits. First, we are not revising our burden estimates because the finalized data validation requirements are similar to existing expectations which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999). Second, we believe that the proposed requirements for conduct of the data validation audits are aligned with methods and procedures which stakeholders currently utilize.

As discussed in section IV.A.3.h.(3)(a)(i) of this rule, due to the proposal to require QCDRs and qualified registries that have never submitted data since the inception of MIPS (CY 2017 MIPS performance period/2019 payment year) through the CY 2020 MIPS performance period/2022 payment year to submit a participation plan as part of their self-nomination for CY 2023 MIPS performance period, we refer readers to section V.B.8.c.(2) of this rule for details on the adjusted burden.

As discussed in section V.B.8.c.(2) of this rule, due to the proposal related to new rejection criteria for QCDR measures, we estimate that the annual burden will range from 855 hours (90 QCDRs × 9.5 hr) to 1,035 hours (90 QCDRs × 11.5 hr) at a cost ranging from $81,413 (855 hr × $95.22/hr) and $98,553 (1,035 hr × $95.22/hr).

(g) Assumptions & Limitations

We note several limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the CY 2022 performance year/2024 payment year. Due to the PHE for COVID–19, we are aware that there may be changes in health care delivery and billing patterns that will impact results for the 2022 performance year/2024 payment year that we are not able to model with our historic data sources. The scoring model results presented in this proposed rule assume that CY 2019 Quality Payment Program data submissions and performance are representative of CY 2022 Quality Payment Program data submissions and performance. The estimated performance for the CY 2022 performance year/2024 payment year using CY 2019 Quality Payment Program data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2019 MIPS performance period/2021 MIPS payment year was significantly lower (30 out of 100 points) than the performance threshold for the 2022 performance year/2024 payment year (75 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in in the CY 2019 Quality Payment Program and submitted data would continue to elect to opt-in in the CY 2022 performance year/2024 payment year. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the proposed policies.

There are additional limitations to our estimates in addition to the limitations described throughout the methodology sections: (1) To the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 129; and (2) our cost data does not overlap with CY 2019 so we may not be capturing performance for all clinicians. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented the estimated impact on total allowed charges by specialty.

1. Alternatives Considered for Utilization Data in PFS Ratesetting

As discussed earlier in this section II.C.1 (Changes in Relative Value Unit (RVU) Impacts), our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2021 with payment rates for CY 2022 using CY 2020 Medicare utilization. As an alternative to using CY 2020 data, we considered using CY 2019 utilization data for the purposes of determining the proposed CY 2022 RVUs, as well as in determining the proposed CY 2022 budget neutrality adjustment and conversion factor. We considered using CY 2019 data due to the PHE for COVID–19, which has impacted the delivery of health care services over the past 18 months. Increases in remote delivery of services to reduce risk of exposure to both practitioner and patients, as well as postponement of elective procedures have resulted in a change to service utilization patterns across Medicare FFS payment systems. Specific to the PFS, overall service utilization decreased by approximately 20 percent in CY 2020 compared to CY 2019, which caused us to question whether CY 2020 data is the

best available data to use for CY 2022 ratesetting.

In order to determine if lower overall utilization in CY 2020 would result in differential impacts on specialties and practitioners, we modeled the PFS ratesetting process using CY 2019 utilization data. We found that the use of CY 2020 as opposed to CY 2019 data in establishing payment rates had relatively little differential impacts on payment, despite the approximately 20 percent decrease in overall service utilization. Table 134 illustrates specialty-specific impacts using CY 2019 data.

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TABLE 134: CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty using CY 2019 Claims

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$265	0%	-2%	0%	-2%
Anesthesiology	$1,971	0%	1%	0%	1%
Audiologist	$75	0%	-1%	0%	-1%
Cardiac Surgery	$255	0%	0%	0%	0%
Cardiology	$7,087	0%	-1%	0%	-1%
Chiropractic	$743	0%	1%	0%	0%
Clinical Psychologist	$884	0%	0%	0%	0%
Clinical Social Worker	$922	0%	0%	0%	0%
Colon And Rectal Surgery	$172	0%	0%	0%	0%
Critical Care	$375	0%	0%	0%	0%
Dermatology	$3,971	0%	0%	0%	0%
Diagnostic Testing Facility	$750	0%	-1%	0%	0%
Emergency Medicine	$3,116	0%	0%	0%	0%
Endocrinology	$575	0%	2%	0%	2%
Family Practice	$6,676	0%	2%	0%	2%
Gastroenterology	$1,799	0%	0%	0%	0%
General Practice	$443	0%	2%	0%	2%
General Surgery	$2,059	0%	0%	0%	0%
Geriatrics	$202	0%	1%	0%	2%
Hand Surgery	$256	0%	2%	0%	2%
Hematology/Oncology	$1,903	0%	-2%	0%	-2%
Independent Laboratory	$650	0%	-2%	0%	-2%
Infectious Disease	$657	0%	-1%	0%	-1%
Internal Medicine	$11,327	0%	1%	0%	1%
Interventional Pain Mgmt	$1,002	0%	1%	0%	0%
Interventional Radiology	$483	0%	-9%	0%	-8%
Multispecialty Clinic/Other Phys	$158	0%	0%	0%	0%
Nephrology	$2,457	0%	0%	0%	0%
Neurology	$1,582	0%	1%	0%	1%
Neurosurgery	$810	0%	0%	0%	0%
Nuclear Medicine	$53	0%	-1%	0%	-1%
Nurse Anes / Anes Asst	$1,251	0%	1%	0%	1%
Nurse Practitioner	$5,476	0%	1%	0%	1%
Obstetrics/Gynecology	$679	0%	1%	0%	1%
Ophthalmology	$5,365	0%	0%	0%	0%
Optometry	$1,388	0%	1%	0%	1%
Oral/Maxillofacial Surgery	$81	0%	-3%	0%	-3%
Orthopedic Surgery	$3,891	0%	1%	0%	1%
Other	$49	0%	0%	0%	0%
Otolarngology	$1,344	0%	-1%	0%	-1%
Pathology	$1,237	0%	-1%	0%	-1%
Pediatrics	$71	2%	2%	0%	5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Physical Medicine	$1,204	0%	0%	0%	0%
Physical/Occupational Therapy	$4,861	0%	0%	0%	0%
Physician Assistant	$3,115	0%	1%	0%	1%
Plastic Surgery	$380	0%	1%	0%	1%
Podiatry	$2,256	0%	1%	0%	1%
Portable X-Ray Supplier	$95	0%	10%	0%	10%
Psychiatry	$1,200	0%	1%	0%	1%
Pulmonary Disease	$1,704	0%	1%	0%	1%
Radiation Oncology And Radiation Therapy Centers	$1,825	0%	-5%	0%	-5%
Radiology	$5,064	0%	-1%	0%	-1%
Rheumatology	$615	0%	0%	0%	0%
Thoracic Surgery	$341	0%	0%	0%	0%
Urology	$1,945	0%	0%	0%	0%
Vascular Surgery	$1,269	0%	-7%	0%	-7%
Total	$100,377	0%	0%	0%	0%

The majority of specialties experienced shifts of less than a percent when we used CY 2019 data, as opposed to CY 2020 data, as displayed in Table 123, as the basis for setting rates. Several specialties shifted by approximately one percent. We did not detect a pattern of specialties that were notably affected by the choice of claims data, either positively or negatively. While Pediatrics shifted from a 1 percent impact when we used CY 2020 claims data to a 5-payment impact when we used CY 2019 claims data, this shift is likely due to the smaller amount of allowed charges associated with the Pediatrics specialty.

We analyzed the percentage change in total RVUs per practitioner. Using CY 2019 utilization data, Total RVUs change between -1 percent and 1 percent for 53 percent of practitioners, representing more than 48 percent of the changes in Total RUs for all practitioners, similar to the results we found when using CY 2020 claims that we discussed in section II.C.1. Variations by specialty were also similar to the results we found using CY 2020 claims and are contained in the public use file that describes the percentage change in total RVUs per practitioner.

Similar to the process described in section II.C.1. of this proposed rule, we used CY 2019 claims data to estimate the CY 2021 PFS CF to be 33.6184 which reflects a budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, which we estimated to be −0.04 using CY 2019 data, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.75 percent fee schedule payment increase for CY 2021 provided by the CAA. The anesthesia CF, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments, would shift by a similar magnitude as the PFS CF. Thus, the estimated PFS CF and anesthesia CF using CY 2019 data is slightly higher compared to using claims data for CY 2020 with an estimated difference of 0.0336 (a little less than three and half cents). We note that the budget neutrality adjustment will be recalculated for the CY 2022 PFS final rule and the use of CY 2019 claims may or may not be higher than the use of CY 2020 claims based on which policies are ultimately finalized.

2. Alternatives Considered for Clinical Labor Pricing Update

As discussed in the PE section of this rule (section II.B. of this proposed rule), we are proposing to update the clinical labor pricing for CY 2022, in conjunction with the final year of the supply and equipment pricing update. We believe it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. We noted in regard to the specialty impacts in Table 123 that the proposed clinical labor pricing update will have a significant effect on the valuation of many services. We have occasionally implemented significant updates based on new data through a phased transition across several calendar years.

For example, we utilized a 4-year transition for the market-based supply and equipment pricing update which will conclude in CY 2022. We considered, as an alternative, the use of a similar 4-year transition to implement the clinical labor pricing update that could smooth out the increases and decreases caused by the pricing update for affected stakeholders. In order to evaluate a phased approach to the clinical labor pricing update, we modeled the PFS ratesetting process using clinical labor prices which transitioned one quarter of the distance to their fully implemented updated price. Table 135 illustrates specialty-specific impacts using the first year of a potential 4-year phase-in for clinical labor pricing:

TABLE 135: CY 2022 PFS Estimated Impact on Total Allowed Charges by Specialty using the First Year of a 4-Year Clinical Labor Pricing Transition

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Allergy/Immunology	$220	0%	0%	0%	0%
Anesthesiology	$2,755	0%	1%	0%	1%
Audiologist	$58	0%	0%	0%	0%
Cardiac Surgery	$203	0%	-1%	0%	-1%
Cardiology	$6,119	0%	-1%	0%	-1%
Chiropractic	$617	0%	0%	0%	0%
Clinical Psychologist	$814	0%	0%	0%	0%
Clinical Social Worker	$873	0%	0%	0%	0%
Colon And Rectal Surgery	$144	0%	0%	0%	0%
Critical Care	$367	0%	0%	0%	0%
Dermatology	$3,454	0%	1%	0%	1%
Diagnostic Testing Facility	$682	0%	5%	0%	5%
Emergency Medicine	$2,525	0%	0%	0%	0%
Endocrinology	$506	0%	1%	0%	1%
Family Practice	$5,725	0%	1%	0%	1%
Gastroenterology	$1,476	0%	0%	0%	0%
General Practice	$368	0%	1%	0%	1%
General Surgery	$1,738	0%	0%	0%	0%
Geriatrics	$175	0%	1%	0%	1%
Hand Surgery	$222	0%	1%	0%	1%
Hematology/Oncology	$1,737	0%	-1%	0%	-1%
Independent Laboratory	$552	0%	0%	0%	0%
Infectious Disease	$639	0%	0%	0%	0%
Internal Medicine	$9,906	0%	0%	0%	1%
Interventional Pain Mgmt	$900	0%	2%	0%	2%
Interventional Radiology	$480	0%	-5%	0%	-5%
Multispecialty Clinic/Other Phys	$138	0%	0%	0%	0%
Nephrology	$2,303	0%	0%	0%	0%
Neurology	$1,354	0%	0%	0%	0%
Neurosurgery	$708	0%	0%	0%	0%
Nuclear Medicine	$50	0%	-1%	0%	-1%
Nurse Anes / Anes Asst	$2,092	0%	1%	0%	1%
Nurse Practitioner	$5,288	0%	0%	0%	1%
Obstetrics/Gynecology	$558	0%	1%	0%	1%
Ophthalmology	$4,365	0%	0%	0%	0%
Optometry	$1,108	0%	0%	0%	0%
Oral/Maxillofacial Surgery	$70	0%	-1%	0%	-1%
Orthopedic Surgery	$3,273	0%	1%	0%	1%
Other	$52	0%	0%	0%	0%
Otolarngology	$1,037	0%	0%	0%	0%
Pathology	$1,061	0%	0%	0%	0%
Pediatrics	$55	0%	0%	0%	0%
Physical Medicine	$1,030	0%	1%	0%	1%
Physical/Occupational Therapy	$3,976	-1%	0%	0%	-1%
Physician Assistant	$2,810	0%	0%	0%	0%
Plastic Surgery	$319	0%	1%	0%	1%
Podiatry	$1,847	0%	1%	0%	1%
Portable X-Ray Supplier	$84	0%	3%	0%	3%
Psychiatry	$1,040	0%	0%	0%	0%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
Pulmonary Disease	$1,471	0%	0%	0%	0%
Radiation Oncology And Radiation Therapy Centers	$1,660	0%	-2%	0%	-2%
Radiology	$4,397	0%	-1%	0%	-1%
Rheumatology	$541	0%	0%	0%	0%
Thoracic Surgery	$302	0%	-1%	0%	-1%
Urology	$1,677	0%	0%	0%	1%
Vascular Surgery	$1,144	0%	-5%	0%	-5%
Total	$89,065	0%	0%	0%	0%

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Table 135 reflects all other proposed policies for CY 2022 with the only difference from Table 123 being the phased approach to updating the clinical labor pricing. Due to the budget neutral nature of PE under the PFS, we do not project that there would be any changes to the conversion factor if we were to use a 4-year transition for clinical labor pricing. We note that a phased transition would delay the full implementation of updated pricing and continue to rely on outdated data for clinical labor pricing.

3. Alternatives Considered for Split (or Shared) Visits

In section II.F of this proposed rule, we proposed to continue our current policy allowing billing of certain ''split'' or ''shared'' evaluation and management (E/M) visits by a physician, when the visit is performed in part by both a physician and an NPP, who are in the same group and the physician performs a substantive portion of the visit. We proposed to codify in our regulations a definition of a split (or shared) visit as an E/M visit in the facility setting that is performed in part by both a physician and NPP who are in the same group, in accordance with applicable laws and regulations, such that the E/M visit could be billed by either the physician or the NPP if it were furnished independently by only one of them in the facility setting (rather than as a split (or shared) visit). We proposed that the physician or NPP who performed the substantive portion of the split (or shared) visit would bill for the visit. We proposed to define substantive portion as more than half of the total time spent by the physician and NPP.

We considered several alternative approaches. First, we considered the option of proposing to disallow split (or shared) visit billing beginning in CY 2022. Under this alternative, in settings where payment for ''incident to'' services is prohibited, physicians and NPPs would only be able to bill for visits they furnish in their entirety under their own NPI. Such a policy would be administratively simple, and reduce the likelihood of paying significantly more than the actual resource costs incurred. When physicians and practitioners furnish services in facility settings, they do not ordinarily incur the cost of clinical staff or other PE costs involved in furnishing the services. When the physician bills for an E/M visit, in accordance with section 1833(a)(1)(N) of the Act, the Medicare Part B payment is equal to 80 percent of the payment basis under the PFS which, under section 1848(a)(1) of the Act, is the lesser of the actual charge or the full fee schedule amount for the service. In contrast, if the NPP bills for it, in accordance with section 1833(a)(1)(O) of the Act, the Medicare Part B payment is equal to 80 percent of the lesser of the actual charge or 85 percent of the fee schedule rate. Because of this payment differential and the lower resource costs associated with E/M visits performed partly by a physician and partly by an NPP, it could be argued that the physician should not be able to bill for such a visit and be paid at the higher fee schedule amount. However, our understanding is that longstanding clinical practice relies substantially upon shared visits between physicians and NPPs in facility settings. To avoid the potential disruption in this common medical practice approach, we did not choose to propose to disallow billing for split (or shared) visits and we are instead seeking comment to confirm current practice patterns and whether there is a need for this kind of split billing, and how often.

We also considered, but did not propose, several alternatives for how to define the substantive portion of split (or shared) visit. We considered proposing to define ''substantive portion'' as any face-to-face portion of the split (or shared) visit, consistent with our current definition. We do not believe it would be appropriate to consider just any portion of the visit—with or without direct patient contact—as a substantive portion. For instance, we do not believe it would be appropriate to consider a brief or trivial interaction, with or without direct patient contact, such as where the physician merely ''pokes their head'' into the room, to be a substantive portion of the visit. We do not believe it would be appropriate to permit a physician to bill for a visit if they do not substantially participate in the visit, given that physicians are paid under the PFS at a higher rate than NPPs. Therefore, we are proposing to define ''substantive portion'' as more than half of the total time spent by the physician or NPP.

Another alternative we considered, but did not propose, was to utilize the medical decision making (MDM) to define substantive portion. We did not choose this approach because MDM is not easily attributed to a single physician or NPP when the work is shared, because MDM is not necessarily quantifiable and can depend on patient characteristics (for example, risk). We believe that time is a more precise factor than MDM to use as a basis for deciding which practitioner performs the substantive portion of the visit. We believe that using the time spent by each practitioner furnishing the split (or shared) visit would provide a more precise metric than potentially finding a way to parse MDM between the physician and the NPP.

We also considered defining substantive portion as performance of the history and/or physical exam, which are key components of certain E/M visits. Given recent changes in the CPT E/M Guidelines, history and physical exam are no longer necessarily included in all E/M visits, because for office/

outpatient E/M visits, the visit level can now be selected based on either MDM or time, and history and exam are performed only as medically appropriate. Also, the CPT Editorial Panel is considering removing history and physical exam as key visit components for institutional visits, similar to the changes already made for office/outpatient E/M visits. Accordingly, defining ''substantive portion'' as any key component including history or exam is not a viable approach.

Lastly, we considered not defining substantive portion in this proposed rule and instead leaving determinations regarding the substantive portion to MAC and/or medical review discretion. However, this approach would impose a significant burden on MACs to assess individual cases and could lead to too much regional variation in payment. We seek public comment to help inform what we consider to be the ''substantive portion'' of a split (or shared) visit in institutional settings and assist us in consideration of our proposed definition of ''substantive portion''.

We considered disallowing split (or shared) billing in critical care, skilled nursing facility (SNF) and nursing facility (NF) visits, as well as new patient and initial patient visits. We require certain SNF/NF visits to be provided entirely by a physician, but we believe we should allow shared visit billing for other visits that can be shared in these settings. (We refer readers to our Conditions of Participation in 42 CFR 483.30 for information regarding the SNF/NF visits that are required to be performed in their entirety by a physician. That regulation requires that certain SNF/NF visits must be furnished directly and solely by a physician). However, we believe current clinical practice generally allows sharing of critical care visits by appropriately trained and qualified practitioners, and we are seeking comment on this belief and this alternative considered. We proposed to allow split (or shared) visit billing in critical care because we believe the practice of medicine has evolved towards a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by clinicians in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued current policy may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of EHRs and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care.

We are proposing to allow split (or shared) visits for both new and established patients as well as initial and subsequent visits. After conducting an internal review, including consulting our medical officers, we believe that the practice of medicine has evolved toward a more team-based approach to care, and greater integration in the practice of physicians and NPPs, particularly when care is furnished by practitioners in the same group in the facility setting. Given this evolution in medical practice, the concerns that may have been present when we issued the manual instructions may no longer be as relevant. We understand that there have been changes in the practice of medicine over the past several years, some facilitated by the advent of electronic health records (EHRs) and other systems, toward a more team-based approach to care. There has also been an increase in alternative payment models that employ a more team-based approach to care. In considering and reevaluating our policy, we see no reason to preclude the physician or NPP from billing for split (or shared) visits for a new patient, in addition to an established patient, or for initial and subsequent split (or shared) visits. Therefore, we are proposing to permit the physician or NPP to bill for split (or shared) visits for both new and established patients, as well as for initial and subsequent visits. We believe this approach is also consistent with the CPT E/M Guidelines for split (or shared) visits, which does not exclude these types of visits from being billed when furnished as split (or shared) services.

4. Alternatives Considered for Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802, 414.806)

This provision implements new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of the CAA (for the purposes of this section of this proposed rule, hereinafter is referred to as ''section 401''). These new requirements will improve the accuracy of reported prices and limit the use of WAC-based pricing.

As discussed in section III.D.1. of this proposed rule, section 1847A(c)(6)(A) of the Act incorporates the definition of manufacturer at section 1927(k)(5) of the Act, but permits the Secretary to exempt repackagers from the definition of manufacturer, as determined appropriate, for purposes of section 1847A(f)(2) of the Act.

We considered whether to implement the flexibility afforded by the statute. However, implementing the flexibility afforded by the statute could potentially lead to a gap in the ASP reporting requirements, meaning that ASPs could be distorted to the extent that certain sales are carved out of the reporting requirement through the use of repackagers.

As discussed previously in this regulatory impact analysis, we are unable to quantitatively estimate the impacts of this provision. We welcome comments on our approach, and on the alternative relative to: (1) The likely costs or savings (to manufacturers, beneficiaries, the government, and other stakeholders); and (2) any other related impacts of this provision.

5. Alternatives Considered for the MDPP Expanded Model Emergency Policy

For the MDPP Expanded Model Emergency Policy, no alternatives were considered. The 2-year MDPP service period has depressed interest in MDPP among would-be MDPP suppliers. These proposed actions address stakeholder comments on the barriers to MDPP expanded model success. If we do not take action, we will not be able to scale MDPP as intended, impacting Medicare beneficiary access to this program. Reducing the MDPP from a 24- to a 12-month services period, increasing the year 1 performance payments, and waiving the Medicare provider enrollment application fee not only better aligns the model with the evidence that helped certify the DPP model test initially, but it will encourage eligible organizations to enroll as MDPP suppliers.

6. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran a separate proposed policies RIA model based on the actual mean for the CY 2019 performance period/2021 payment year with a performance threshold of 86 and an additional performance threshold of 92 points, which are potential values that may be used for the CY 2022 performance period/2024 payment year. The model with a performance threshold of 86 and additional performance threshold of 92 has the same mean and median final score as our proposed policies RIA model since the performance threshold does not change the final score. We estimate that $ 885 million would be redistributed through budget neutrality.

For clinicians who meet or exceed the additional performance threshold, an additional $294 million was distributed. The maximum positive payment adjustment would be 15.5 percent prior to the maximum additional payment adjustment and 25.5 percent after considering the MIPS maximum positive payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 70.3 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

We report the findings for the baseline RIA model which describes the impact for the 2022 MIPS performance period/2024 MIPS payment year if this regulation did not exist. The baseline RIA model has a final score mean of 78.13 and median of 82.59. We estimate that $428 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 6.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 8.3 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

H. Impact on Beneficiaries

We do not believe these provisions will have a negative impact on beneficiaries given overall PFS budget neutrality.

1. Requiring Certain Manufacturers To Report Drug Pricing Information for Part B (§§ 414.802, 414.806)

Section 1927(b)(3)(A)(iii) of the Act requires manufacturers with a Medicaid drug rebate agreement to report ASP data consistent with the information required for such reporting at section 1847A of the Act. Some manufacturers without Medicaid drug rebate agreements voluntarily submit ASP data for their single source drugs or biologicals that are payable under Part B, however other manufacturers without Medicaid drug rebate agreements do not voluntarily submit such data. Without manufacturer reported ASP data, CMS cannot calculate the ASP payment limit, and consequently, payment is typically based on Wholesale Acquisition Cost (WAC).

Consistent with section 1847A(c)(3) of the Act and our regulations at § 414.804(a)(2), the ASP is net of price concessions. However, consistent with the definition of WAC at section 1847A(c)(6)(B) of the Act, the WAC is not net of price concessions and is thus nearly always, and sometimes significantly, higher than ASP. Drugs with payment allowances based on WAC may have greater ''spreads'' between acquisition costs and payment than drugs for which there is an ASP-based payment allowance, which, in turn, may: (1) Incent the use of the drug based on its spread rather than on purely clinical considerations; (2) result in increased payments under Medicare Part B; and (3) result in increased beneficiary cost sharing. This provision implements new statutory requirements under sections 1847A and 1927 of the Act, as amended by section 401 of Division CC, Title IV of the CAA, 2021. These new requirements will improve the accuracy of reported payment limits and limit the use of WAC-based pricing.

For single source drugs, these changes may result in lower payment limits because, typically, the WAC plus 3 percent is higher than ASP plus 6 percent. This then translates to cost savings for both the government and beneficiaries, who will pay coinsurance on a lesser amount. However, for the reason stated earlier in this regulatory impact analysis (see section VII.G.4. of this proposed rule), we are unable to predict the magnitude of this effect.

Similarly, payment limits for multiple source drugs could increase or decrease, and we are unable to predict the direction or magnitude of specific or aggregate effects at this time.

We welcome comment on: (1) The likely costs or savings to beneficiaries; and (2) other related impacts of this provision.

2. Determination of ASP for Certain Self-Administered Drug Products

Although we are unable to quantify the total magnitude of the potential savings, these changes have the potential to substantially reduce program expenditures and beneficiary coinsurance. The OIG's July 2020 report (discussed in section III.D.2. of this proposed rule) determined that the inclusion of self-administered versions of certolizumab and abatacept in their respective volume-weighted, average ASPs, alone, has resulted in $173 million in additional Medicare beneficiary coinsurance between 2014 and 2018.

The proposed regulatory changes have the potential to result in decreased payment limits for identified billing and payment codes and could, in turn, substantially reduce beneficiary coinsurance. Since section 405 of Division CC, Title IV of the CAA, 2021 directs CMS to implement the statutory changes at section 1847A(g)(3) of the Act beginning on July 1, 2021, these potential savings may be observed within the year.

We welcome comment on: (1) The likely costs or savings to beneficiaries; and (2) other related impacts of this provision.

3. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

This change will have a positive impact on eligible MDPP beneficiaries, as it better aligns with the CDC's National DPP, giving both the participants and the coaches similar messaging around this program, regardless of payer. MDPP suppliers often offer the MDPP set of services to mixed cohorts, or classes with participants who are not eligible for MDPP, but who are enrolled in a National DPP cohort. Since MDPP generally follows the CDC's National DPP and aligns its program with the CDC's DPRP Standards, it is confusing to participants, coaches, and staff when talking about a 2-year program to its eligible Medicare participants when the non-Medicare participants have a 1-year program. Finally, reducing the MDPP service period from 2 years to one (1) year allows more cohorts to start and finish MDPP during the expanded model initial period of performance, which ends in March 2023.

4. Quality Payment Program

There are several changes in this rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup proposals if finalized will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipate this will improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new measures include patient-reported outcome-based measures, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors

frequently of interest to patients when making decisions about treatment.

K. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's proposed rule will be the number of reviewers of last year's rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters will review this year's rule in detail, and it is also possible that some reviewers will choose not to comment on the rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of last year's rule. We welcome any comments on the approach in estimating the number of entities which will review this rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We are seeking comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $913.92 (8.0 hours × $114.24). Therefore, we estimated that the total cost of reviewing this regulation is $36,764,260 ($885.92 × 40,227 reviewers on last year's proposed rule).

J. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 132 and 133 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2021 to CY 2022 based on the FY 2022 President's Budget baseline.

TABLE 136: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2022 Annualized Monetized Transfers	Estimated increase in expenditures of $2.7 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 137: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2022 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.7 billion
From Whom to Whom?	Beneficiaries to Federal Government.

K. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health insurance, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

■ 2. In § 403.902:

■ a. Amend the definition of ''Ownership or investment interest'' by adding paragraphs (3)(vi) and (vii);

■ b. Add the definition of ''Physician-owned distributorship'' in alphabetical order; and

■ c. Revise the definition of ''Short term medical supply or device loan''.

The additions and revision read as follows:

§ 403.902 Definitions.

* * * * *

Ownership or investment interest

* * *

(3) * * *:

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under section 401(a) of the Internal Revenue Code of 1986.

* * * * *

Physician-owned distributorship, for the purposes of determining the existence of a reportable ownership or investment interest under this subpart, means an entity that:

(1) Meets the definition of an applicable manufacturer or applicable group purchasing organization as defined in this section, and

(2) Meets at least one of the following two conditions:

(i) Has a minimum of 5 percent direct or indirect ownership or investment interest in the applicable manufacturer or applicable group purchasing organization held by a physician or a physician's immediate family member, or

(ii) A physician or a physician's immediate family member receives compensation from the applicable manufacturer or group purchasing organization in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from the sale or distribution of devices by the applicable manufacturer or group purchasing organization in which the physician or physician's immediate family member has ownership.

(3) This physician owned distributor definition does not apply for purposes of any other laws or regulations, including, but not limited to, section 1877 of the Act, the regulations at 42 CFR part 411, subpart J, section 1128B of the Act, or the regulations at 42 CFR 1001.952.

* * * * *

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 cumulative days per calendar year or a quantity of 90 cumulative days of average daily use per calendar year, to permit evaluation of the device or medical supply by the covered recipient.

* * * * *

■ 3. Amend § 403.904 by adding paragraph (a)(3) to read as follows:

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) * * *

(3) An applicable manufacturer or applicable group purchasing organization that has reported payments or transfers of value under the scope of this section may not remove, delete, or alter any record/(s) unless an error is discovered in the information that had been furnished, or the record is otherwise believed to meet exceptions for reporting.

* * * * *

■ 4. Amend § 403.908 by revising paragraph (c)(3) and adding paragraph (c)(4) to read as follows:

§ 403.908 Procedures for electronic submission of reports.

* * * * *

(c) * * *

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information. These points of contact must be updated for 2 years following record submission.

(4) An applicable manufacturer or applicable group purchasing organization that meets the definition of physician-owned distributorship as defined in § 403.902 must identify its status as a physician-owned distributorship when registering or recertifying.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 5. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 6. Amend § 405.902 by adding the definitions of ''Additional documentation'', ''Additional documentation request (ADR)'', ''Post-payment medical review'', and ''Prepayment medical review'' in alphabetical order to read as follows:

§ 405.902 Definitions.

Additional documentation means any information requested by a contractor when conducting a prepayment review or post-payment review.

Additional documentation request (ADR) means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review.

* * * * *

Post-payment medical review (or post-payment review) means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate.

Prepayment medical review (or prepayment review) means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made.

* * * * *

■ 7. Add § 405.903 to read as follows:

§ 405.903 Prepayment review.

(a) A contractor may select a claim(s) for prepayment review.

(b) In conducting a prepayment review, a contractor may issue additional documentation requests to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45-calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems

good cause in accepting the documentation.

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after the 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) A contractor's prepayment review will result in an initial determination under § 405.920.

■ 8. Add § 405.929 under the ''Initial Determinations'' heading in Subpart I to read as follows:

§ 405.929 Post-payment review.

(a) A contractor may select a claim(s) for post-payment review, which is conducted under the reopening authority in § 405.980.

(b) In conducting a post-payment review, a contractor may issue an additional documentation request to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) The outcome of a contractor's review will result in either no change to the initial determination or a revised determination under § 405.984.

■ 9. Add § 405.930 under the ''Initial Determinations'' heading in Subpart I to read as follows:

§ 405.930 Failure to respond to additional documentation request.

If a contractor gives a provider or supplier notice and time to respond to an additional documentation request and the provider or supplier does not provide the additional documentation in a timely manner, the contractor has authority to deny the claim.

■ 10. Amend § 405.986 by revising paragraph (a) introductory text to read as follows:

§ 405.986 Good cause for reopening.

(a) *Establishing good cause for reopening.* Good cause may be established when—

* * * * *

■ 11. Amend § 405.2411 by—

■ a. Revising paragraph (b)(2);

■ b. Redesignating paragraph (b)(3) as (4); and

■ c. Adding a new paragraph (b)(3).

The revision and addition read as follows:

§ 405.2411 Scope of benefits.

* * * * *

(b) * * *

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife or clinical psychologist employed or under contract with the RHC or FQHC at the time the services are furnished;

(3) Inclusive of hospice attending physician services, and are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant designated by the patient at the time of hospice election as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished; and

* * * * *

■ 12. Amend § 405.2446 by revising paragraph (c) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(c) FQHC services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility, other institution used as a patient's home, or are hospice attending physician services furnished during a hospice election.

* * * * *

■ 13. Amend § 405.2462 by—

■ a. Redesignating paragraphs (c) through (g) as paragraphs (e) through (i), respectively;

■ b. Revising paragraphs (a) through (c)

■ c. Adding new paragraph (d); and

■ d. In newly redesignated paragraph (e) introductory text, by removing the reference to ''paragraph (d)'' and adding in its place the reference to ''paragraph (f)''.

The additions and revisions read as follows:

§ 405.2462 Payment for RHC and FQHC services.

(a) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate, subject to a payment limit per visit determined in paragraph (b) of this section, for each beneficiary visit for covered services. This rate is determined by the Medicare Administration Contractor (MAC), in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(b) *RHC payment limit per visit.* (1) In establishing limits on payment for rural health clinic services provided by rural health clinics the limit for services provided prior to April 1, 2021:

(i) In 1988, after March 31, at $46 per visit; and

(ii) In a subsequent year (before April 1, 2021), at the limit established for the previous year increased by the percentage increase in the Medicare Economic Index (MEI) (as defined in section 1842(i)(3) of the Act) applicable to primary care services (as defined in section 1842(i)(4) of the Act) furnished as of the first day of that year.

(2) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by rural health clinics or any rural health clinic that is enrolled on or after January 1, 2021 under section 1866(j) of the Act), the limit for services provided:

(i) In 2021, after March 31, at $100 per visit;

(ii) In 2022, at $113 per visit;

(iii) In 2023, at $126 per visit;

(iv) In 2024, at $139 per visit;

(v) In 2025, at $152 per visit;

(vi) In 2026, at $165 per visit;

(vii) In 2027, at $178 per visit; and

(viii) In 2028, at $190 per visit.

(ix) In a subsequent year, at the limit established for the previous year increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such year.

(3) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by provider-based rural health clinics as described in

section (c)(4) of this part, the limit for services provided:

(i) In 2021, after March 31, at an amount equal to the greater of:

(A) For rural health clinics that had an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021, or

(*2*) The payment limit per visit applicable in paragraph (2) of this section.

(B) For rural health clinics that did not have an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2021, or

(*2*) The payment limit per visit applicable in paragraph (2) of this section.

(ii) In a subsequent year, at an amount equal to the greater of:

(A) The amount established under paragraph (b)(3)(i)(A) or (B) of this section, as applicable for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year, or

(B) The payment limit per visit applicable under paragraph (2) of this section for such subsequent year.

(c) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* (1) An RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

(i) An integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(ii) Operated with other departments of the provider under common licensure, governance and professional supervision.

(2) An RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraphs (b)(1) and (2) of this part, for each beneficiary visit for covered services when in a hospital with greater than 50 beds as determined in § 412.105(b) of this chapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(3) Prior to April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate and is not subject to a payment limit per visit described in paragraphs (b)(1) and (2) of this part for each beneficiary visit for covered services when in a hospital with less than 50 beds as determined in § 412.105(b) of this chapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(4) On or after April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraph (b)(3) of this part, for each beneficiary visit for covered services when it meets the specified qualifications in paragraph(d) of this part. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(d) *Specified qualifications.* A provider-based rural health clinic must meet the following qualifications to have a payment limit per visit established in accordance with section (b)(3) of this part.

(1) As of December 31, 2020, was in a hospital with less than 50 beds (as determined in § 412.105(b) of this chapter) and after December 31, 2020 in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the COVID–19 Public Health Emergency (PHE)); and one of the following circumstances:

(i) As of December 31, 2020, was enrolled under section 1866(j) of the Act (including temporary enrollment during the COVID–19 PHE); or

(ii) Submitted an application for enrollment under section 1866(j) of the Act (or a request for temporary enrollment during the COVID–19 PHE) that was received not later than December 31, 2020.

(2) [Reserved]

* * * * *

■ 14. Amend § 405.2463 by revising paragraphs (a)(1)(i) introductory text, and (b)(3) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

(a) * * *

(1) * * *

(i) Face-to-face encounter (or, for mental health disorders only, an encounter that meets the requirements under paragraph (b)(3) of this section) between an RHC patient and one of the following:

* * * * *

(b) * * *

(3) *Visit—Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder between an RHC or FQHC patient and one of the following:

* * * * *

■ 15. Amend § 405.2466 by revising paragraph (b)(1)(iv) to read as follows:

§ 405.2466 Annual reconciliation.

* * * * *

(b) * * *

(1) * * *

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, and COVID–19 vaccine and their administration is 100 percent of Medicare reasonable cost.

* * * * *

■ 16. Amend § 405.2469 by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 17. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 18. Amend § 410.33 by revising paragraphs (c), (g)(6)(i), (g)(6)(ii), (g)(8)(i), (g)(8)(ii), and (g)(9) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(c) *Nonphysician personnel.* (1) Except as otherwise stated in paragraph (c)(2) of this section, any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(2) For services that do not require direct or in-person beneficiary interaction, treatment, or testing, any nonphysician personnel used by the IDTF to perform the tests must meet all applicable State licensure requirements for doing so. If there are any applicable State licensure requirements, the IDTF must maintain documentation available for review that these requirements are met.

* * * * *

(g) * * *

(6) * * *

(i) Except as otherwise stated in paragraph (g)(6)(ii) of this section, have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

(A) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and

(B) Notify the CMS designated contractor in writing of any policy changes or cancellations.

(ii) Paragraph (g)(6)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

* * * * *

(8) * * *

(i) Except as otherwise stated in paragraph (g)(8)(ii) of this section, answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(A) The name, address, telephone number, and health insurance claim number of the beneficiary.

(B) The date the complaint was received, the name of the person receiving the complaint, and a summary of actions taken to resolve the complaint.

(C) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(ii) Paragraph (g)(8)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(9) Openly post these standards for review by patients and the public. (This requirement does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.)

* * * * *

■ 19. Amend § 410.37 by adding paragraph (j) to read as follows:

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

* * * * *

(j) Effective January 1, 2022, colorectal cancer screening tests include a planned screening flexible sigmoidoscopy or screening colonoscopy that involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

■ 20. Amend § 410.47 by—

■ a. Revising the section heading as set forth below;

■ b. In paragraph (a), revising the definitions of ''Individualized treatment plan'', ''Medical director'', Outcomes assessment'', ''Physician prescribed exercise'', ''Psychosocial assessment'', and ''Supervising physician'';

■ c. Revising paragraphs (b), (c), (d), and (e);

■ d. Removing paragraph (f).

■ e. Redesignating paragraph (g) as new paragraph (f).

The revisions read as follows:

§ 410.47 Pulmonary rehabilitation program: Conditions of coverage.

(a) * * *

Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

Medical director means the physician who oversees the pulmonary rehabilitation program at a particular site.

Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes the following:

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

(ii) Objective clinical measures of exercise performance and self-reported measures of shortness of breath and behavior.

* * * * *

Physician-prescribed exercise means aerobic exercise, combined with other types of exercise (such as conditioning, breathing retraining, step, and strengthening) as determined to be appropriate for individual patients by a physician.

Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

* * * * *

Supervising physician means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

(b) *General rule.* (1) *Covered conditions.* Medicare Part B covers pulmonary rehabilitation for beneficiaries:

(i) With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease;

(ii) Who were hospitalized with a COVID–19 diagnosis and experience persistent symptoms, including respiratory dysfunction, for at least four weeks after hospital discharge;

(iii) Additional medical indications for coverage for pulmonary

rehabilitation may be established through a national coverage determination (NCD).

(2) *Components.* Pulmonary rehabilitation must include all of the following components:

(i) Physician-prescribed exercise during each pulmonary rehabilitation session.

(ii) Education or training that is closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

(iii) Psychosocial assessment.

(iv) Outcomes assessment.

(v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings.* (i) Medicare Part B pays for pulmonary rehabilitation in the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have the following:

(A) A physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

(B) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease.

(c) *Medical director standards.* The physician responsible for a pulmonary rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(d) *Supervising physician standards.* Physicians acting as the supervising physician must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(e) *Limitations on coverage:* The number of pulmonary rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

* * * * *

■ 21. Amend § 410.49 by—

■ a. In paragraph (a), revising the definition of ''Medical director'', revising paragraph (i) in the definition of ''Outcomes assessment'', and revising the definition of ''Physician-prescribed exercise''; and

■ b. Revising paragraphs (b)(1) introductory text, (b)(2) paragraph heading and introductory text, (b)(2)(ii), (b)(3)(i) introductory text, (d) paragraph heading and introductory text, (e) paragraph heading and introductory text, and (f).

The revisions read as follows:

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) * * *

Medical director means the physician who oversees the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

Outcomes assessment * * *

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

* * * * *

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as strengthening and stretching) as determined to be appropriate for individual patients by a physician.

* * * * *

(b) * * *

(1) *Covered conditions.* Medicare Part B covers cardiac rehabilitation and intensive cardiac rehabilitation for beneficiaries who have experienced one or more of the following:

* * * * *

(2) *Components.* Cardiac rehabilitation and intensive cardiac rehabilitation must include all of the following:

* * * * *

(ii) Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the individual's needs.

* * * * *

(3) * * *

(i) Medicare Part B pays for cardiac rehabilitation and intensive cardiac rehabilitation in the following settings:

* * * * *

(d) *Medical director standards.* The physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

* * * * *

(e) *Supervising physician standards.* Physicians acting as the supervising physician must possess all of the following:

* * * * *

(f) *Limitations on coverage.* (1) Cardiac rehabilitation: The number of cardiac rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

(2) *Intensive cardiac rehabilitation:* Intensive cardiac rehabilitation sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

■ 22. Amend § 410.59 by—

■ a. Revising paragraph (a)(4)(iii)(B); and

■ b. Adding paragraphs (a)(4)(iv) and (v).

The revision and additions read as follows:

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) * * *

(4) * * *

(iii) * * *

(B) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a

15-minute timed code, a portion of a unit of service separately from the part furnished by the occupational therapist such that the minutes for that portion of a service (or unit of a service) furnished by the occupational therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the occupational therapy assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the occupational therapist and occupational therapy assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes and no more than 28 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the occupational therapist.

* * * * *

■ 23. Amend § 410.60 by—

■ a. Revising paragraph (a)(4)(iii)(B); and

■ b. Adding paragraphs (a)(4)(iv) and (v).

The revision and additions read as follows:

§ 410.60 Outpatient physical therapy services: Conditions.

(a) * * *

(4) * * *

(iii) * * *

(B) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a 15-minute timed code, a portion of a unit of service separately from the part furnished by the physical therapist such that the minutes for that portion of a service (or unit of a service) furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day, when the physical therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the physical therapist and physical therapist assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant and one unit is billed without the prescribed modifier for the service provided by the physical therapist.

* * * * *

■ 24. Amend § 410.67 by—

■ a. In paragraph (b), revising paragraphs (3) and (4) in the definition of ''Opioid use disorder treatment service'';

■ b. Revising paragraphs (d)(4)(ii) and (iii), and (d)(5);

■ c. Adding paragraph (d)(6).

The revisions and addition read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service * * *

(3) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(4) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

(d) * * *

(4) * * *

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this chapter.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this chapter.

(5) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment or an adjustment to the bundled payment under paragraph (d)(4)(i) of this section is considered a duplicative payment if a claim for delivery, administration or dispensing of the same medications for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS will recoup the duplicative payment made to the opioid treatment program.

(6) When substance use counseling under paragraph (b)(3) of this section or therapy services under paragraph (b)(4) of this section are furnished using audio-only telephone calls after the end of the Public Health Emergency as defined in § 400.200 of this chapter, the practitioner must document in the beneficiary's medical record that the services were furnished using audio-only technology and the rationale for doing so. For purposes of the adjustment to the bundled payment under paragraph (d)(4)(i)(A) of this section, the practitioner must also certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

* * * * *

■ 25. Add § 410.72 to read as follows:

§ 410.72 Registered dietitians' and nutrition professionals' services.

(a) *Definition: Registered dietitians and nutrition professionals.* Meet the qualifications at § 410.134.

(b) *Covered registered dietitian and nutrition professional services.* Medicare Part B covers:

(1) *Coverage condition.* Medical nutrition therapy (MNT) services as defined at § 410.130 under the conditions of coverage at § 410.132.

(2) *Other services.* Registered dietitians and nutrition professionals may also provide diabetes self-management (DSMT) services if they are or represent an accredited DSMT entity and have an order from a physician or qualified nonphysician practitioner who is treating the patient's diabetic condition.

(3) *Limits on MNT and DSMT.* (i) DSMT and MNT cannot be furnished to a patient on the same date of service, and

(ii) MNT and DSMT services cannot be furnished incident to the professional services of a physician or nonphysician practitioner service.

(c) *Limitations.* The following services are not registered dietitian or nutrition professional services for purposes of billing Medicare Part B:

(1) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating hospital.

(2) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating SNF.

(3) Services furnished by a registered dietitian or nutrition professional to a patient in a Medicare-participating ESRD facility in accordance with the limitation on coverage of MNT service listed at § 410.132(b)(1).

(d) *Professional services.* Registered dietitians and nutrition professionals can be paid for professional services only when the services have been personally performed by them.

(e) *Telehealth services.* MNT and DMST services may be provided as telehealth service (meeting the requirements in § 410.78) when registered dietitians or nutrition professionals act as distant site practitioners.

(f) *Restrictions.* The services are provided on an assignment-related basis, and a registered dietitian or nutrition professional may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the registered dietitian or nutrition professional must make the appropriate refund to the beneficiary.

■ 26. Amend § 410.74 by revising paragraph (a)(2)(v) to read as follows:

§ 410.74 Physician assistants' services.

(a) * * *

(2) * * *

(v) Prior to January 1, 2022, furnishes services that are billed by the employer of a physician assistant; and

* * * * *

■ 27. Amend 410.78 by—

■ a. Revising paragraph (a)(3); and

■ b. Adding paragraphs (b)(3)(xiii) and (xiv), and (b)(4)(iv)(D).

The revision and additions read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph, multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology. A modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met.

* * * * *

(b) * * *

(3) * * *

(xiii) A rural emergency hospital (as defined in section 1861(kkk)(2) of the Act), for services furnished on or after January 1, 2023.

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services furnished on or after the first day after the end of the PHE as defined in our regulation at § 400.200. Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and at least once within 6 months prior to the initial telehealth service and at least once within 6 months before any subsequent Medicare telehealth service.

(4) * * *

(iv) * * *

(D) Services furnished on or after the first day after the end of the PHE as defined in our regulation at § 400.200 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

* * * * *

■ 28. Amend § 410.79 by—

■ a. Revising paragraph (c)(1)(ii);

■ b. Removing the second duplicate paragraph (c)(3)(ii); and

■ c. Revising paragraph (e)(3)(v)(C).

The revisions read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(c) * * *

(1) * * *

(ii) An MDPP beneficiary is eligible for the first ongoing maintenance session interval only if the beneficiary:

(A) Starts his or her first core session on or before December 31, 2021;

(B) Attends at least one in-person core maintenance session during the final core maintenance session interval; and

(C) Achieves or maintains the required minimum weight loss at a minimum of one in-person core maintenance session during the final core maintenance session interval.

* * * * *

(e) * * *

(3) * * *

(v) * * *

(C) Beneficiaries who began the set of MDPP services between January 1, 2021 and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

* * * * *

■ 29. Amend § 410.105 by—

■ a. Revising paragraph (d)(3)(ii); and
■ b. Adding paragraphs (d)(3)(iii) and (iv).

The revision and additions read as follows:

§ 410.105 Requirements for coverage of CORF services.

* * * * *

(d) * * *

(3) * * *

(ii) Except as provided in paragraph (d)(3)(iii) of this section, furnishes a portion of a service, or in the case of a 15-minute timed code, a portion of a unit of service, separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service (or unit of a service) exceed 10 percent of the total time for that service (or unit of a service).

(iii) Paragraph (d)(3)((ii) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the physical or occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant or occupational therapy assistant.

(iv) Where there are two remaining 15-minute units to bill of the same service and the physical therapist and the physical therapist assistant or the occupational therapist and the occupational therapy assistant, as applicable, each provided between 9 and 14 minutes, with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant or occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the physical therapist or occupational therapist.

■ 30. Amend § 410.130 by—
■ a. Revising the definition of ''Chronic renal insufficiency''; and
■ b. Removing the definition of ''Treating physician''.

The revision reads as follows:

§ 410.130 Definitions.

* * * * *

Chronic renal insufficiency means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 15–59 ml/min/1.73m2).

* * * * *

■ 31. Amend § 410.132 by revising paragraphs (a), (b)(5), and (c) to read as follows.

§ 410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT services.* Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by a physician.

(b) * * *

(5) An exception to the maximum number of hours in paragraphs (b)(2), (3), and (4) of this section may be made when a physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

(c) *Referrals.* Referral may only be made by a physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this subpart with documentation noted by a referring physician in the beneficiary's medical record.

■ 32. Amend § 410.150 by revising paragraph (b)(15) to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(15)(i) Prior to January 1, 2022, to the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies provided incident to his or her services. Payment is made to the employer of a physician assistant regardless of whether the physician assistant furnishes services under a W–2, employer-employee employment relationship, or whether the physician assistant is an independent contractor who receives a 1099 reflecting the relationship. Both types of relationships must conform to the appropriate guidelines provided by the Internal Revenue Service. A qualified employer is not a group of physician assistants that incorporate to bill for their services. Payment is made only if no facility or other provider charges or is paid any amount for services furnished by a physician assistant.

(ii) Effective on or after January 1, 2022, payment is made to a physician assistant for professional services furnished by a physician assistant in all settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of professional services of the physician assistant.

* * * * *

■ 33. Amend § 410.152 by revising paragraphs (l) introductory text and (l)(5) to read as follows:

§ 410.152 Amounts of payment.

* * * * *

(l) *Amount of payment: Preventive services.* Except as provided otherwise in this paragraph, Medicare Part B pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the furnished by a provider or supplier for the following preventive services:

* * * * *

(5) Colorectal cancer screening tests (excluding barium enemas).

(i) For the colorectal cancer screening tests described in § 410.37(j) of this part, Medicare Part B pays at the specified percentage as follows:

(A) 80 percent for CY 2022.

(B) 85 percent for CY 2023 through 2026.

(C) 90 percent for 2027 through 2029.

(D) 100 percent beginning January 1, 2030.

(ii) [Reserved]

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 34. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 35. Amend § 411.351 by revising the definition of ''List of CPT/HCPCS Codes'' to read as follows:

§ 411.351 Definitions.

* * * * *

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are designated health services under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated each calendar quarter and posted on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.*

* * * * *

■ 36. Amend § 311.354 by—
■ a. Revising paragraphs (c)(2)(ii)(A)(*2*) and (*3*);
■ b. Adding paragraph (c)(2)(ii)(A)(*4*); and
■ c. Revising paragraph (c)(2)(ii)(B).

The revisions and addition read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(A) * * *

(*2*) Is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation that positively correlates with the number or value of the physician's referrals to the entity;

(*3*) Is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services as a variable, resulting in an increase or decrease in the amount of compensation per unit that positively correlates with the physician's generation of other business for the entity; or

(*4*) Is payment for anything other than services personally performed by the physician (or immediate family member).

(B) For purposes of applying paragraph (c)(2)(ii)(A) of this section:

(*1*) A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(*2*) The individual unit is:

(*i*) Time, where the compensation paid to the physician (or immediate family member) is based solely on the period of time during which the services are provided.

(*ii*) Service, where the compensation paid to the physician (or immediate family member) is based solely on the service provided.

(*iii*) Time, where the compensation paid to the physician (or immediate family member) is not based solely on the period of time during which a service is provided or based solely on the service provided.

(*3*) Services that are personally performed by a physician (or immediate family member) do not include services that are performed by any person other than the physician (or immediate family member), including, but not limited to, the referring physician's (or immediate family member's) employees, independent contractors, group practice members, or persons supervised by the physician (or the immediate family member).

* * * * *

■ 37. Amend § 411.355 by revising paragraph (h) to read as follows:

§ 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

* * * * *

(h) *Preventive screening tests and vaccines.* (1) Preventive screening tests and vaccines that meet the following conditions:

(i) The preventive screening test or vaccine is listed on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph (h) is applicable.

(ii) The preventive screening test or vaccine is covered by Medicare.

(iii) The preventive screening test or vaccine is subject to a CMS-mandated frequency limit.

(2) During such period as the vaccine is not subject to a CMS-mandated frequency limit, paragraph (h)(1)(iii) of this section does not apply to a COVID–19 vaccine identified on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph (h) is applicable.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 38. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 39. Amend § 414.64 by revising paragraph (a) to read as follows:

§ 414.64 Payment for medical nutrition therapy.

(a) *Payment under the physician fee schedule.* Medicare payment for medical nutrition therapy is made under the physician fee schedule in accordance with subpart B of this part. Payment to nonphysician professionals, as specified in paragraph (b) of this section, is 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) or the lesser of the actual charges or 85 percent of the physician fee schedule amount.

* * * * *

■ 40. Amend § 414.84 by—

■ a. Revising paragraphs (b)(1)(i)

■ b. In paragraph (b)(1)(ii) by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022'';

■ c. Revising paragraph (b)(2)(i)

■ d. In paragraph (b)(2)(ii) by removing the reference CY 2018'' and adding in its place the reference ''CY 2022'';

■ e. Revising paragraph (b)(3)(i);

■ f. In paragraph (b)(3)(ii) by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022'';

■ g. Revising paragraph (b)(4)(i)(A);

■ h. In paragraphs (b)(4)(i)(B) and (b)(4)(ii)(B) by removing the reference ''CY 2018'' and adding in its place the reference ''CY 2022''

■ i. Revising paragraph (b)(4)(ii)(A); and

■ j. Revising paragraphs (b)(5), (b)(6)(i), (b)(7)(i) and (ii), and (c).

The revisions read as follows:

§ 414.84 Payment for MDPP Services.

* * * * *

(b) * * *

(1) * * *

(i) For a first core session furnished January 1, 2022 through December 31, 2022 the amount is $26.

* * * * *

(2) * * *

(i) For the fourth core session furnished January 1, 2022 through December 31, 2022 the amount is $78.

* * * * *

(3) * * *

(i) For the ninth core session furnished January 1, 2022 through December 31, 2022 the amount is $130.

* * * * *

(4) * * *

(i) * * *

(A) For a second core maintenance session January 1, 2022 through December 31, 2022 the amount is $106.

* * * * *

(ii) * * *

(A) For a second core maintenance session January 1, 2022 through December 31, 2022 the amount is $52.

* * * * *

(5) *Performance Goal 5: Attends two ongoing maintenance sessions and maintains the required minimum weight loss during an ongoing maintenance session interval.* For an MDPP beneficiary who attends his or her first core session on or before December 31, 2021, CMS makes a performance payment to an MDPP supplier if an MDPP beneficiary attends two ongoing maintenance sessions during an ongoing maintenance session interval, achieves attendance at that second ongoing maintenance session upon attendance at an ongoing maintenance session furnished by that supplier, and achieves or maintains the required minimum weight loss as measured in-person during an ongoing maintenance session furnished during the applicable ongoing maintenance session interval. CMS makes this performance payment to an MDPP supplier only once per MDPP beneficiary per ongoing maintenance session interval. The amount of this performance payment is determined as follows:

(i) For a second ongoing maintenance session furnished in interval 1 (months 13–15 of the MDPP services period), January 1, 2022 through December 31, 2022 the amount is $52.

(ii) For a second ongoing maintenance session furnished in interval 2 (months 16–18 of the MDPP services period), January 1, 2022 through December 31, 2022 the amount is $52.

(iii) For a second ongoing maintenance session furnished in interval 3 (months 19–21 of the MDPP services period), January 1, 2022 through December 31, 2022 the amount is $53.

(iv) For a second ongoing maintenance session furnished in interval 4 (months 22–24 of the MDPP services period), January 1, 2022 through December 31, 2022 the amount is $53.

(v) For a second ongoing maintenance session furnished during a subsequent year. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(6) * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2022 through December 31, 2022 the amount is $189.

* * * * *

(7) * * *

(i) For a core session or core maintenance session, as applicable, furnished January 1, 2022 through December 31, 2022 the amount is $26.

(ii) For a core session or core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2018. The performance payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

(c) *Bridge payment.* CMS makes a bridge payment to an MDPP supplier only for a core session or core maintenance session furnished to an MDPP beneficiary who has previously received MDPP services from a different MDPP supplier. An MDPP supplier that has previously been paid either a bridge payment or a performance payment for an MDPP beneficiary is not eligible to be paid a bridge payment for that beneficiary. A bridge payment is made only on an assignment-related basis in accordance with § 424.55 of this chapter, and MDPP suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount. CMS will make a bridge payment only to an MDPP supplier that complies with all applicable enrollment and program requirements, and only for MDPP services furnished by an eligible coach, on or after his or her coach eligibility start date and, if applicable, before his or her coach eligibility end date. As a condition of payment, the MDPP supplier must report the NPI of the coach who furnished the session on the claim for the MDPP session. The amount of the bridge payment is determined as follows:

(1) For core session or core maintenance session, as applicable, furnished January 1, 2022 through December 31, 2022 the amount is $26.

(2) For core session and core maintenance session, as applicable, furnished during a calendar year subsequent to CY 2022. The bridge payment amount specified in this paragraph, adjusted as specified in paragraph (d) of this section.

* * * * *

■ 41. Amend § 414.626 by revising paragraphs (b)(1) and (f) to read as follows:

§ 414.626 Data reporting by ground ambulance organizations.

* * * * *

(b) * * *

(1) Within 30 days of the date that CMS notifies a ground ambulance organization under paragraph (c)(3) of this section that it has selected the ground ambulance organization to report data under this section, the ground ambulance organization must select a data collection period that corresponds with its annual accounting period and provide the start date of that data collection period to CMS or its contractor.

* * * * *

(f) *Public availability of data.* Beginning in 2024, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

* * * * *

■ 42. Amend § 414.802 by revising the definition of ''Drug'' to read as follows:

§ 414.802 Definitions.

* * * * *

Drug means a drug or a biological, and for purposes of applying section 1847A(f) of the Act, includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

* * * * *

■ 43. Section 414.806 is revised to read as follows:

§ 414.806 Penalties associated with misrepresentation and the failure to submit timely and accurate ASP data.

(a) *Misrepresentation.* Section 1847A(d)(4)(A) specifies the penalties associated with misrepresentations in the reporting of the manufacturer's average sales price for a drug as defined at § 414.802.

(b) *Failure to provide timely information or the submission of false information.* (1) For a manufacturer that has entered into and has in effect a rebate agreement under section 1927 of the Act, section 1927(b)(3)(C) of the Act specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

(2) For a manufacturer that has not entered into and does not have in effect a rebate agreement under section 1927 of the Act, sections 1847A(d)(4)(B) and (C) of the Act specify the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

■ 44. Amend § 414.904 by adding paragraph (d)(4) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(d) * * *

(4) *Payment adjustment for certain drugs for which there is a self-administered version.*

(i) *In general.* Except as provided in paragraphs (d)(4)(ii) and (iii) of this section, if the Inspector General identifies a drug or biological product in a study described in section 1847A(g)(1) of the Act, the Secretary must apply the payment limit for the applicable billing and payment code as specified in paragraph (d)(4)(iv) of this section, beginning with the first day of the second quarter after such study is publicly available. The methodology described in this paragraph will be recalculated each quarter thereafter, except when conditions described in paragraph (d)(4)(ii) are met.

(ii) *Exception.* The adjustment described in paragraph (d)(4)(i) of this section does not apply to the payment limit for a billing and payment code for a quarter if, at the time that ASP calculations are finalized for such quarter, the drug in the dosage form described by the billing and payment code is included by the FDA on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

(iii) *Special rule for certain billing and payment codes.* Effective July 1, 2021, for a billing and payment code described under section 1847A(g)(3) of

the Act, the payment limit for the applicable billing and payment code must be determined as described in paragraph (d)(4)(iv) of this section, and the exception specified at paragraph (d)(4)(ii) of this section does not apply.

(iv) *Lesser-of methodology.* For purposes of this section, the payment limit is the lesser of:

(A) The payment limit determined under section 1847A of the Act for such billing and payment code if each National Drug Code for such product so identified under section 1847A(g)(1) of the Act were excluded from such determination; and

(B) The payment limit otherwise determined under section 1847A of the Act for such billing and payment code without application of section 1847A(g) of the Act.

(v) *NDC changes.* For an Inspector General-identified National Drug Code, as described under section 1847A(g)(1) or (3) of the Act, for which the manufacturer has redesignated the National Drug Code (without changes to the dosage form), the application of the lesser-of methodology described in this paragraph must use manufacturer-reported ASP data associated with the redesignated National Drug Code in the same manner as the one originally identified by the Inspector General.

* * * * *

■ 45. Amend § 414.1300 by revising paragraphs (a)(2) and (3) to read as follows:

§ 414.1300 Basis and scope.

(a) * * *

(2) Section 1848(k)—Quality Reporting System.

(3) Section 1848(m)—Incentive Payments for Quality Reporting.

* * * * *

■ 46. Amend § 414.1305 by—

■ a. Revising the definitions of ''Collection type'' and ''Meaningful EHR user for MIPS'';

■ b. In the definition of ''MIPS determination period'', revising paragraph (2).

■ c. In the definition of ''MIPS eligible clinician'', revising the introductory text, paragraph (2) introductory text, and adding paragraph (3);

■ d. Adding the definitions of ''Multispecialty group'', ''MVP participant'', ''Population health measure'', ''QCDR measure'', ''Single specialty group'', ''Special status'' and ''Subgroup'' in alphabetical order; and

■ e. Revising the definition of ''Submission type''.

The revision and additions read as follows:

§ 414.1305 Definitions.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the CY 2017 through 2022 MIPS performance periods/2019 through 2024 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures.

* * * * *

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.

* * * * *

MIPS determination period means:

* * *

(2) Subject to § 414.1310(b)(1)(iii), an individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold or as having special status, as applicable, during the first segment of the MIPS determination period will be identified as such for the applicable MIPS payment year regardless of the results of the second segment of the MIPS determination period. An individual eligible clinician, group, or APM Entity group for which the unique billing TIN and NPI combination is established during the second segment of the MIPS determination period will be assessed based solely on the results of such segment.

MIPS eligible clinician as identified by a unique billing TIN and NPI combination used to assess performance, means any of the following (except as excluded under § 414.1310(b)):

* * * * *

(2) For the 2021 through 2023 MIPS payment years:

* * * * *

(3) For the 2024 MIPS payment year and future years:

(i) A clinician described in paragraph (2) of this definition;

(ii) A clinical social worker (as defined in section 1861(hh)(1) of the Act);

(ii) A certified nurse midwife (as defined in section 1861(gg)(2) of the Act); and

(vii) A group that includes such clinicians.

* * * * *

Multispecialty group means a group that consists of two or more specialty types as identified by eligible clinicians in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS).

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2025 MIPS performance period/2027 MIPS payment year and future years, MVP Participant means an individual MIPS eligible clinician, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Population health measure means a quality measure that indicates the quality of a population or cohort's overall health and well-being, such as access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.

* * * * *

QCDR measure means a quality measure that is submitted by a QCDR and approved by CMS under § 414.1400. QCDR measures consist of:

(1) Measures that are not included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year; and

(2) Measures that are included in the MIPS final list of quality measures described in § 414.1330(a)(1) for the applicable MIPS payment year, but have undergone substantive changes, as determined by CMS.

* * * * *

Single-specialty group means a group that consists of one specialty type as identified by eligible clinicians in the PECOS.

* * * * *

Special status means that a MIPS eligible clinician:

(1) Meets the definition of an ASC-based MIPS eligible clinician, facility-based MIPS eligible clinician, hospital-based MIPS eligible clinician, non-patient facing MIPS eligible clinician, or is in a small practice; or

(2) Is located in an HPSA or rural area.

Subgroup means a subset of a group which contains at least one MIPS eligible clinician and is identified by a combination of the group TIN, subgroup identifier, and each eligible clinician's NPI.

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) For the CY 2017 through 2022 MIPS performance periods/2019 through 2024 MIPS payment years, the CMS Web Interface.

* * * * *

■ 47. Amend § 414.1310 by revising paragraph (e)(1) to read as follows:

§ 414.1310 Applicability.

* * * * *

(e) * * * (1) Except as provided under §§ 414.1315(a)(2), 414.1317(b), 414.1318(b), and 414.1370(f)(2) each MIPS eligible clinician in the group receives a final score based on the group's combined performance assessment.

* * * * *

■ 48. Amend § 414.1317 by revising paragraph (b)(2) to read as follows:

§ 414.1317 APM Entity groups.

* * * * *

(b) * * *

(2) *Performance category weights.* The cost performance category weight is zero percent of the final score for an APM Entity. The performance category reweighting scenarios under § 414.1380(c)(2) apply to an APM Entity.

* * * * *

■ 49. Section 414.1318 is added to subpart O to read as follows:

§ 414.1318 Subgroups.

(a) *Eligibility and special status.* (1) General. Except as provided under paragraph (a)(2) of this section, for a MIPS payment year, determinations of meeting the low-volume threshold criteria and special status for subgroups are determined at the group level in accordance with §§ 414.1305 and 414.1310.

(2) *Exclusions.* An individual eligible clinician or group that elects to participate in MIPS as a MIPS eligible clinician in accordance with § 414.1310(b)(iii)(A) or § 414.1310(b)(2) is not eligible to participate in a subgroup.

(b) *Final score.* Except as provided under § 414.1317(b), each MIPS eligible clinician in the subgroup receives a final score based on the subgroup's combined performance assessment.

(c) *Subgroup reporting requirements.* For individual eligible clinicians to participate in MIPS as a subgroup, all of the following requirements must be met:

(1) Individual eligible clinicians that elect to participate in MIPS as a subgroup must aggregate their quality and improvement activities performance data across the subgroup's identifier.

(2) Individual eligible clinicians that elect to participate in MIPS as a subgroup will have their performance assessed at the subgroup level across all the MIPS performance categories based on an MVP in accordance with § 414.1365 and on the APM Performance Pathway in accordance with § 414.1367, as applicable. Subgroups that are MVP Participants must adhere to an election process described in § 414.1365(b).

■ 50. Amend § 414.1320 by—

■ a. Redesignating paragraphs (d) through (g) as paragraphs (e) through (h).

■ b. Adding a new paragraph (d).

The addition reads as follows:

§ 414.1320 MIPS performance period.

* * * * *

(d) For purposes of the 2022 MIPS payment year, the performance period for:

(1) The quality and cost performance categories are the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year.

(2) The improvement activities performance categories are a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

* * * * *

■ 51. Amend § 414.1325 by revising paragraph (c)(1) to read follows:

§ 414.1325 Data submission requirements.

* * * * *

(c) * * *

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the CY 2019 MIPS performance period/ 2021 MIPS payment year, for small practices only); and, for the CY2017 through 2022 MIPS performance periods/2019 through 2024 MIPS payment years, CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

* * * * *

■ 52. Amend § 414.1340 by—

■ a. Revising paragraph (a)(3);

■ b. Adding paragraph (a)(4);

■ c. Revising paragraph (b)(3); and

■ d. Adding paragraph (b)(4).

The revisions and additions read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

(a) * * *

(3) At least 70 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2022, 2023, and 2024.

(4) At least 80 percent of the MIPS eligible clinician or group's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment year 2025.

(b) * * *

(3) At least 70 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment years 2022, 2023, and 2024.

(4) At least 80 percent of the applicable Medicare Part B patients seen during the performance period to which the measure applies for MIPS payment year 2025.

* * * * *

■ 53. Amend § 414.1350 by revising paragraph (c)(4) and adding paragraph (c)(6) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(c) * * *

(4) For the procedural episode-based measures specified beginning with the 2019 performance period, the case minimum is 10, unless otherwise specified for individual measures. Beginning with the 2022 performance period, the case minimum for Colon and Rectal Resection procedural episode-based measure is 20 episodes.

* * * * *

(6) For the chronic condition episode-based measures specified beginning with the 2022 performance period, the case minimum is 20.

* * * * *

■ 54. Amend § 414.1360 by revising paragraph (a)(2) to read as follows:

§ 414.1360 Data submission criteria for the improvement activities performance category.

(a) * * *

(2) *Groups and virtual groups.* Beginning with the 2022 performance year, each improvement activity for which groups and virtual groups submit a yes response in accordance with paragraph (a)(1) of this section must be performed by at least 50 percent of the

NPIs that are billing under the group's TIN or virtual group's TINs or that are part of the subgroup, as applicable; and the NPIs must perform the same activity during any continuous 90-day period within the same performance year.

* * * * *

■ 55. Section 414.1365 is added to subpart O to read as follows:

§ 414.1365 MIPS Value Pathways.

(a) *General.* (1) Beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, CMS uses MVPs included in the MIPS final inventory of MVPs established by CMS through rulemaking to assess performance for the quality, cost, improvement activities, and Promoting Interoperability performance categories.

(2) [Reserved]

(b) *MVP/Subgroup registration.* (1) To report an MVP, an MVP Participant must register for the MVP, and if applicable, as a subgroup during a period that begins on April 1 and ends on November 30 of the applicable CY performance period or a later date specified by CMS. To report the CAHPS for MIPS survey associated with an MVP, a group, subgroup or APM Entity must complete their registration by June 30 of such performance period or a later date specified by CMS.

(2) At the time of registration, the MVP Participant must submit the following information, as applicable:

(i) Each MVP Participant must select an MVP, 1 population health measure included in the MVP, and any outcomes-based administrative claims measure on which the MVP Participant intends to be scored.

(ii) Each subgroup must submit a list of each TIN/NPI associated with the subgroup and a plain language name for the subgroup.

(c) *MVP reporting requirements.* (1) Quality. Except as provided in paragraph (c)(1)(i) of this section, an MVP Participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

(i) Paragraph (c)(1) of this section does not apply to a small practice that reports on an MVP that includes fewer than 4 Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

(ii) [Reserved]

(2) *Cost.* An MVP Participant is scored on the cost measures included in the MVP that they select and report.

(3) *Improvement activities.* An MVP Participant who reports an MVP, must report one of the following:

(i) Two medium-weighted improvement activities;

(ii) One high-weighted improvement activity;

(iii) Participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(4) *Foundational layer*—(i) *Promoting interoperability.* An MVP Participant is required to meet the Promoting Interoperability performance category reporting requirements described at § 414.1375(b).

(A) For the CY 2023 and 2024 performance periods/2025 and 2026 MIPS payment years, an MVP Participant that is a subgroup is required to submit its affiliated group's data for the Promoting Interoperability performance category.

(B) [Reserved]

(ii) *Population health measures.* Each MVP Participant is scored on 1 population health measure in accordance with paragraph (d)(1) of this section.

(d) *MVP scoring*—(1) *General.* An MVP Participant that is not an APM Entity is scored on measures and activities included in the MVP in accordance with paragraphs (d)(1) through (3) of this section. An MVP Participant that is an APM Entity is scored on measures and activities included in the MVP in accordance with § 414.1317(b).

(2) *Performance standards.* Unless otherwise indicated in this paragraph (d), the performance standards described at § 414.1380(a)(1)(i) through (iv) apply to the measures and activities included in the MVP.

(3) *Performance categories.* An MVP Participant is scored under MIPS in four performance categories.

(i) *Quality performance category.* Except as provided in paragraphs (d)(3)(i)(A)(1) and (B) of this section, the quality performance category score for MVP Participants is calculated in accordance with § 414.1380(b)(1) based on measures included in the MVP.

(A) *Population health measures.* Except as provided in paragraph (d)(3)(i)(A)(1) of this section, each selected population health measure that does not have a benchmark or meet the case minimum requirement is excluded from the MVP participant's total measure achievement points and total available measure achievement points.

(*1*) Subgroups are scored on each selected population health measure that does not have a benchmark or meet the case minimum requirement based on their affiliated group score, if available. If the subgroup's affiliated group score is not available, each such measure is excluded from the subgroup's total measure achievement points and total available measure achievement points.

(*2*) [Reserved]

(B) *Outcomes-based administrative claims measures.* MVP Participants receive zero measure achievement points for each selected outcomes-based administrative claims measure that does not have a benchmark or meet the case minimum requirement.

(ii) *Cost performance category.* The cost performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(2)(i) through (v) and the cost measures included in the MVP that they select and report.

(iii) *Improvement activities performance category.* The improvement activities performance category score is calculated based on the submission of high- and medium-weighted improvement activities. MVP Participants will receive 20 points for each medium-weighted improvement activity and 40 points for each high-weighted improvement activity required under § 414.1360 on which data is submitted in accordance with § 414.1325 or for participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice, as described at § 414.1380(b)(3)(ii).

(iv) *Promoting interoperability performance category.* The Promoting Interoperability performance category score is calculated for an MVP Participant using the methodology at § 414.1380(b)(4), except as provided in paragraph (d)(3)(iv)(A) of this section.

(A) If a subgroup does not submit its affiliated group's data for the Promoting Interoperability performance category, the subgroup will receive a score of zero for the Promoting Interoperability performance category.

(B) [Reserved]

(e) *Final score calculation.* The final score is calculated for an MVP Participant using the methodology at § 414.1380(c), unless otherwise indicated in this paragraph (e).

(1) *MVP performance category weights.* For an MVP Participant that is not an APM Entity, the final score is calculated using the performance category weights described at § 414.1380(c)(1). For an MVP Participant that is an APM Entity, the final score is calculated using the performance category weights described at § 414.1317(b).

(2) *Reweighting MVP performance categories*—(i) *General reweighting.* For an MVP Participant that is not an APM Entity, in accordance with paragraph (e)(2)(iii) of this section, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in the circumstances described at § 414.1380(c)(2)(i)(A)(*2*) through (*9*) and § 414.1380(c)(2)(i)(C). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

(ii) *Subgroups.* For an MVP Participant that is a subgroup, any reweighting applied to its affiliated group will also be applied to the subgroup. In addition, if reweighting is not applied to the affiliated group, the subgroup may receive reweighting in the following circumstances independent of the affiliated group:

(A) A subgroup may submit an application to CMS demonstrating that it was subject to extreme and uncontrollable circumstances and receive reweighting in accordance with § 414.1380(c)(2)(i)(A)(*6*) and § 414.1380(c)(2)(i)(C)(*2*). In the event that a subgroup submits data for a performance category, the scoring weight described at § 414.1380(c)(1) would be applied and its weight would not be redistributed.

(B) A subgroup will receive reweighting if CMS determines, based on information known to the agency prior to the beginning of the relevant MIPS payment year, that data for the subgroup are inaccurate, unusable or otherwise compromised due to circumstances outside of the control of the subgroup and its agents, in accordance with § 414.1380(c)(2)(i)(A)(*9*) and § 414.1380(c)(2)(i)(C)(*10*).

(iii) *Reweighting scenarios.* For an MVP Participant that is not an APM Entity, a scoring weight different from the weights described at § 414.1380(c)(1) will be assigned to a performance category, and its weight as described at § 414.1380(c)(1) will be redistributed to another performance category or categories, in accordance with § 414.1380(c)(2)(ii). For an MVP Participant that is an APM Entity, the performance category weights will be redistributed in accordance with § 414.1317(b).

(3) *Facility-based scoring.* If an MVP Participant, that is not an APM Entity, is eligible for facility-based scoring, a facility-based score also will be calculated in accordance with § 414.1380(e).

(4) *Complex patient bonus.* A complex patient bonus will be added to the final score for an MVP Participant in accordance with § 414.1380(c)(3).

■ 56. Amend § 414.1375 by—

■ a. Revising paragraphs (b)(2)(ii);

■ b. Revising paragraphs (b)(3) paragraph heading and (b)(3)(ii) introductory text; and

■ c. Adding paragraph (b)(3)(iii).

The revisions and additions read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(b) * * *

(2) * * *

(ii) Beginning with the 2021 MIPS payment year:

(A) Report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs;

(B) For each required measure, as applicable, report the numerator (of at least one) and denominator, or yes/no statement, or an exclusion for each measure that includes an option for an exclusion; and

(C) Beginning with the 2024 MIPS payment year, report that the MIPS eligible clinician completed the actions included in the SAFER Guides measure during the year in which the performance period occurs.

(3) *Engaging in activities related to supporting providers with the performance of CEHRT; support for health information exchange and the prevention of information blocking; actions to limit or restrict the compatibility or interoperability of CEHRT.* * * *

* * * * *

(ii) *Support for health information exchange and the prevention of information blocking.* For the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician must attest to CMS that he or she—

* * * * *

(iii) *Actions to limit or restrict the compatibility or interoperability of CEHRT.* Beginning with the 2024 MIPS payment year, the MIPS eligible clinician must attest to CMS that he or she—

(A) Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

(B) [Reserved]

■ 57. Amend § 414.1380 by—

■ a. Revising paragraphs (b)(1)(i) introductory text, and(b)(1)(i)(A)(*1*);

■ b. Adding paragraphs (b)(1)(i)(A)(*3*) and (b)(1)(i)(C);

■ c. Revising paragraphs (b)(1)(iii) and (b)(1)(iv)(B);

■ d. Revising paragraphs (b)(1)(v)(A) introductory text and (b)(1)(v)(B) introductory text;

■ e. Adding paragraph (b)(1)(v)(B)(*1*)(*iii*);

■ f. Revising paragraphs (b)(1)(vi)(C) introductory text, (b)(1)(vi)(C)(*4*), (b)(1)(vi)(E), (b)(1)(vii) introductory text, (b)(1)(vii)(A), (b)(2)(iii) introductory text and (b)(2)(v) introductory text;

■ g. Adding paragraphs (b)(2)(v)(A) and (B);

■ h. Revising paragraph (b)(4)(ii) introductory text and (b)(4)(ii)(C);

■ i. Revising the table in paragraph (c) introductory text;

■ j. Revising paragraph (c)(2)(i)(A)(*4*);

■ k. Removing and reserving paragraph (c)(2)(i)(A)(*5*);

■ l. Revising paragraphs (c)(2)(i)(C)(*9*), (c)(2)(ii)(A) and (c)(2)(ii)(F);

■ m. Adding paragraph (c)(2)(ii)(G);

■ n. Revising paragraph (c)(3);

■ o. Revising paragraph (e)(6)(iv) through (vi).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) *Measure achievement points.* For the CY 2017 through 2021 performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. Except as provided under paragraph (b)(1)(i)(C) of this section, beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians receive between 1 and 10 measure achievement points (including partial points) for each such measure. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible

clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

(A) * * *

(*1*) Except as provided in paragraphs (b)(1)(i)(A)(2) and (3) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement. Beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians other than small practices receive 0 measure achievement points for each such measure, and small practices receive 3 measure achievement points for each such measure.

* * * * *

(*3*) Beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians receive 5 measure achievement points for each submitted new measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

* * * * *

(C) *New measures.* (1) Beginning with the CY 2022 performance period/2024 MIPS payment year, MIPS eligible clinicians receive between 5 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340.

(2) For purposes of this section, ''new measure'' means a quality measure that is in its first 2 years in the program.

* * * * *

(iii) *Minimum case requirements.* Except as otherwise specified in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

(iv) * * *

(B) Except as provided in paragraph (b)(1)(iv)(B)(1) of this section, beginning with the 2021 MIPS payment year, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(*1*) For the CY 2022 MIPS performance period/2024 MIPS payment year, MIPS eligible clinicians receive no more than 7 measure achievement points for each measure (except for measures in the CMS Web Interface) for which the applicable benchmark is identified as topped out for 2 or more consecutive years based on the historical benchmarks published for the CY 2021 MIPS performance period and continues to be identified as topped out based on the performance period benchmarks published for the CY 2022 MIPS performance period.

(2) [Reserved]

* * * * *

(v) * * *

(A) *High priority measures.* Subject to paragraph (b)(1)(v)(A)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 2 measure bonus points for each outcome and patient experience measure and 1 measure bonus point for each other high priority measure. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians do not receive such measure bonus points for CMS Web Interface measures.

* * * * *

(B) *End-to-end electronic reporting.* Subject to paragraph (b)(1)(v)(B)(*1*) of this section, for the CY 2017 through 2021 MIPS performance periods/2019 through 2023 MIPS payment years, MIPS eligible clinicians receive 1 measure bonus point for each measure (except claims-based measures) submitted with end-to-end electronic reporting for a quality measure under certain criteria determined by the Secretary.

(*1*) * * *

(*iii*) Beginning in the 2024 MIPS payment year, MIPS eligible clinicians will no longer receive measure bonus for submitting using end-to-end electronic reporting.

* * * * *

(vi) * * *

(C) The improvement percent score is assessed at the performance category level for the quality performance category and included in the calculation of the quality performance category score as described in paragraph (b)(1)(vii) of this section.

* * * * *

(*4*) Beginning with the CY 2018 performance period/2020 MIPS payment year, we will assume a quality performance category achievement percent score of 30 percent if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

* * * * *

(E) For the purpose of improvement scoring methodology, the term ''improvement percent score'' means the score that represents improvement for the purposes of calculating the quality performance category score as described in paragraph (b)(1)(vii) of this section.

* * * * *

(vii) *Quality performance category score.* A MIPS eligible clinician's quality performance category score is the sum of all the measure achievement points assigned for the measures required for the quality performance category criteria plus the measure bonus points in paragraph (b)(1)(v) of this section. The sum is divided by the sum of total available measure achievement points. The improvement percent score in paragraph (b)(1)(vi) of this section is added to that result. The quality performance category score cannot exceed 100 percentage points.

(A) For each measure that is submitted, if applicable, and impacted by significant changes or errors prior to the applicable data submission deadline at § 414.1325(e), performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or CMS determines that they may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes or errors'' means changes to or errors in a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes or errors include, but are not limited to, changes to codes (such as ICD–10, CPT,

or HCPCS codes) or the active status of codes, the inadvertent omission of codes or inclusion of inactive or inaccurate codes, or changes to clinical guidelines or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the data submission deadline at § 414.1325(e)(1).

* * * * *

(2) * * *

(iii) The cost performance category score is the sum of the following, not to exceed 100 percent:

* * * * *

(v) A cost performance category score is not calculated if a MIPS eligible clinician or group is not attributed any cost measures for the performance period because the clinician or group has not met the minimum case volume specified by CMS for any of the cost measures or a benchmark has not been created for any of the cost measures that would otherwise be attributed to the clinician or group.

(A) Beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score. For purposes of this paragraph (b)(2)(v)(A), ''significant changes'' are changes external to the care provided, and that CMS determines may lead to misleading or inaccurate results. Significant changes include, but are not limited to, rapid or unprecedented changes to service utilization, and will be empirically assessed by CMS to determine the extent to which the changes impact the calculation of a cost measure score that reflects clinician performance.

(B) [Reserved]

* * * * *

(4) * * *

(ii) Beginning with the 2019 performance period/2021 MIPS payment year, a MIPS eligible clinician's Promoting Interoperability performance category score equals the sum of the scores for each of the required measures and any applicable bonus scores, not to exceed 100 points.

* * * * *

(C) Each optional measure is worth five or ten bonus points, as specified by CMS.

* * * * *

(c) * * *

Table 1 to paragraph (c) introductory text

For the 2019 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)], not to exceed 100 points.
For the 2020 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + [the complex patient bonus + the small practice bonus], not to exceed 100 points.
Beginning with the 2021 MIPS payment year:
Final score = [(quality performance category score × quality performance category weight) + (cost performance category score × cost performance category weight) + (improvement activities performance category score × improvement activities performance category weight) + (Promoting Interoperability performance category score × Promoting Interoperability performance category weight)] × 100 + the complex patient bonus, not to exceed 100 points.

* * * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) *For the Promoting Interoperability performance category:* (i) For the 2021 through 2024 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*ii*) For the 2019 through 2024 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*iii*) For the 2024 MIPS payment year, the MIPS eligible clinician is a clinical social worker. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance

category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(C) * * *

(9) For the 2020 MIPS payment year through the 2023 MIPS payment year the MIPS eligible clinician demonstrates through an application submitted to CMS that they are in a small practice as defined in § 414.1305, and overwhelming barriers prevent them from complying with the requirements for the Promoting Interoperability performance category. Beginning with the 2024 MIPS payment year the MIPS eligible clinician is in a small practice as defined in § 414.1305.

* * * * *

(ii) * * *

(A) For the 2019 MIPS payment year:

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Table 2 to paragraph (c)(2)(ii)(A)

Performance category (%)	Weighting for the 2019 MIPS payment year (%)	Reweight scenario if no promoting interoperability performance category score (%)	Reweight scenario if no quality performance category score (%)	Reweight scenario if no improvement activities performance category score (%)
Quality	60	85	0	75
Cost	0	0	0	0
Improvement Activities	15	15	50	0
Promoting Interoperability	25	0	50	25

* * * * *

(F) Except as provided in paragraph (c)(2)(ii)(G) of this section, beginning with the 2024 MIPS payment year:

Table 7 to paragraph (c)(2)(ii)(F)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	55	30	15	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

(G) For small practices beginning with the 2024 MIPS payment year:

Table 8 to paragraph (c)(2)(ii)G)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	40	30	30	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	50	0	50	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

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* * * * *

(3) *Complex patient bonus.* For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, provided that a MIPS eligible clinician, group, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as stated in paragraphs (c)(3)(i) through (c)(3)(iv) of this section. Beginning with the CY 2022 MIPS performance period/CY 2024 MIPS payment year, provided that a MIPS eligible clinician, group, subgroup, virtual group or APM Entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, if applicable, as described in paragraphs (c)(3)(v) through (c)(3)(viii) of this section.

(i) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for MIPS eligible clinicians and groups, the complex patient bonus is calculated as follows: [The average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group] + [the dual eligible ratio × 5].

(ii) For the CY 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, for APM Entities and virtual groups, the complex patient bonus is calculated as follows: [The beneficiary weighted average HCC risk score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively] + [the average dual eligible ratio for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively, × 5].

(iii) For the 2020, 2021, 2022, and 2023 MIPS payment years and associated performance periods, the complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 and 2023 MIPS payment years and associated performance periods, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii) of this section, and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

(v) Beginning with the CY 2022 MIPS performance period/CY2024 MIPS payment year, the complex patient bonus is limited to MIPS eligible clinicians, groups, subgroups, APM Entities, and virtual groups with a risk indicator at or above the risk indicator calculated median.

(vi) Beginning with the CY2022 MIPS performance period/CY2024 MIPS payment year, for MIPS eligible clinicians, groups, and subgroups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5+4* associated HCC standardized score calculated with the average HCC risk score assigned to beneficiaries (pursuant to the HCC risk adjustment model established by CMS pursuant to section 1853(a)(1) of the Act) seen by the MIPS eligible clinician or seen by clinicians in a group or subgroup; social complex patient bonus component = 1.5+4* associated dual proportion standardized score. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(vii) Beginning with the CY2022 MIPS performance period/CY2024 MIPS payment year, for APM Entities and

virtual groups, the complex patient bonus components are calculated as follows for the specific risk indicators: Medical complex patient bonus component = 1.5+4* the beneficiary weighted average HCC risk standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation within the APM Entity or virtual group, respectively; social complex patient bonus component = 1.5+4* the average dual proportion standardized score for all MIPS eligible clinicians, and if technically feasible, TINs for models and virtual groups which rely on complete TIN participation, within the APM Entity or virtual group, respectively. The components are added together to calculate one overall complex patient bonus. A standardized score for each risk indicator is determined based on the mean and standard deviation of the raw risk indicator score and provides a standardized measurement of how far each risk score is from the mean: (raw risk indicator score − risk indicator mean)/risk indicator standard deviation.

(viii) Beginning with the CY2022 MIPS performance period/CY2024 MIPS payment year, the complex patient bonus cannot exceed 10.0 and cannot be below 0.0.

* * * * *

(e) * * *

(6) * * *

(iv) *Quality.* The quality performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS quality performance category score for those MIPS-eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS quality performance category

(v) *Cost.* The cost performance category score is established by determining the percentile performance of the facility in the value-based purchasing program for the specified year as described in paragraph (e)(1) of this section and awarding a score associated with that same percentile performance in the MIPS cost performance category score for those MIPS eligible clinicians who are not eligible to be scored using facility-based measurement for the MIPS payment year. A clinician or group receiving a facility-based performance score will not earn improvement points based on prior performance in the MIPS cost performance category.

(A) *Other cost measures.* MIPS eligible clinicians who are scored under facility-based measurement are not scored on cost measures described in paragraph (b)(2) of this section.

(B) [Reserved]

(vi) *Use of score from facility-based measurement.* The MIPS quality and cost performance category scores will be based on the facility-based measurement scoring methodology described in paragraph (e)(6) of this section unless:

(A) For the CY 2019 MIPS performance period/2021 MIPS payment year, through the CY 2021 MIPS performance period/2023 MIPS payment year, a clinician or group receives a higher combined MIPS quality and cost performance category score through another MIPS submission.

(B) Beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, a clinician or group receives a higher MIPS final score through another MIPS submission.

■ 58. Amend § 414.1395 by revising paragraph (c) to read as follows:

§ 414.1395 Public reporting.

* * * * *

(c) *New measures and activities.* (1) CMS does not publicly report any data on new quality or cost measure for the first 2 years in which it is in the program, after which CMS evaluates the measure to determine whether it is suitable for public reporting under paragraph (b) of this section.

(2) CMS does not publicly report any MVP data on new improvement activity or Promoting Interoperability measure, objective, or activity included in an MVP for the first year in which it is included in the MVP.

* * * * *

■ 59. Revise § 414.1400 to read as follows:

§ 414.1400 Third party intermediaries.

(a) *General.* (1) MIPS data may be submitted on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity by any of the following third party intermediaries:

(i) QCDR;

(ii) Qualified registry;

(iii) Health IT vendor; or

(iv) CMS-approved survey vendor.

(2) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(A) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(B) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(C) All data must be submitted in the form and manner specified by CMS.

(D) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(E) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(F) Prior to discontinuing services to any MIPS eligible clinician, group, virtual group, subgroup, or APM Entity during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, virtual group, subgroup, or APM Entity to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and

(B) Whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

(3) All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Such certification must be made in a form and manner and at such time as specified by CMS.

(b) *Additional requirements for QCDRs and qualified registries*—(1) *General.* (i) Beginning with the CY 2021 MIPS performance period/2023 MIPS payment year, QCDRs and qualified registries must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) For qualified registries, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

(*1*) The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(*2*) [Reserved]

(ii) Beginning with the 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP.

(2) *Self-nomination.* For the 2018 and 2019 MIPS performance periods/2020 and 2021 MIPS payment years, entities seeking to qualify as a QCDR or qualified registry must self-nominate September 1 until November 1 of the CY preceding the applicable performance period. For the 2020 MIPS performance period/2022 MIPS payment year and future years, entities seeking to qualify as a QCDR or qualified registry must self-nominate during a 60-day period during the CY preceding the applicable performance period (beginning no earlier than July 1 and ending no later than September 1). Entities seeking to qualify as a QCDR or qualified registry for a performance period must provide all information required by CMS at the time of self-nomination and must provide any additional information requested by CMS during the review process. For the 2019 MIPS performance period/2021 MIPS payment year and future years, existing QCDRs and qualified registries that are in good standing may attest that certain aspects of their previous year's approved self-nomination have not changed and will be used for the applicable performance period.

(3) *Conditions for approval.* (i) Beginning with the 2020 MIPS performance period/2022 MIPS payment year, the QCDR or qualified registry must have at least 25 participants by January 1 of the year prior to the applicable performance period.

(ii) If an entity seeking to qualify as a QCDR or qualified registry uses an external organization for purposes of data collection, calculation, or transmission, it must have a signed, written agreement with the external organization that specifically details the responsibilities of the entity and the external organization. The written agreement must be effective as of September 1 of the year preceding the applicable performance period.

(iii) Beginning with the 2021 MIPS performance period/2023 MIPS payment year, the QCDR or qualified registry must provide performance feedback to their clinicians and groups at least 4 times a year, and provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the performance period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).

(iv) Beginning with the 2023 MIPS performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination for CMS's approval and may not change the plan once approved without the prior approval of the agency.

(v) Beginning with the 2021 MIPS performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct annual data validation audits in accordance with this paragraph (b)(3)(v) of this section.

(A) The QCDR or qualified registry must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program.

(B) The QCDR or qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR or qualified registry must conduct data validation on data for each submitter type for which it will submit data, including MIPS eligible clinicians, groups, virtual groups, subgroups, APM entities, voluntary participants, and opt-in participants, if applicable.

(D) The QCDR or qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR or qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR or qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR or qualified registry may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each QCDR or qualified registry data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, subgroup, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each data validation audit, including the overall data deficiencies or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or error, and, how and when each deficiency or data error type was corrected.

(*1*) QCDRs and qualified registries must conduct validation on the data they intend to submit for the MIPS performance period and provide the results of the executed data validation plan by May 31st of the year following the performance period.

(*2*) [Reserved]

(vi) Beginning with the 2021 MIPS performance period/2023 MIPS payment year, the QCDR or qualified registry must conduct targeted audits in accordance with this paragraph (b)(3)(vi).

(A) If a data validation audit under paragraph (b)(3)(v) of this section identifies one or more deficiency or data error, the QCDR or qualified registry must conduct a targeted audit into the impact and root cause of each such

deficiency or data error for that MIPS payment year.

(B) The QCDR or qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR or qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(3)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR or qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(vii) For the 2023 MIPS performance period/2025 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for any of the 2019 through 2023 MIPS payment years must submit a participation plan for CMS's approval. The participation plan must include the QCDR and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(viii) Beginning with the 2024 MIPS performance period/2026 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS's approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(4) *QCDR measures for the quality performance category*—(i) *QCDR measure self-nomination requirements.* For the 2018 MIPS performance period/2020 MIPS payment year and future years, at the time of self-nomination an entity seeking to become a QCDR must submit the following information for any measure it intends to submit for the payment year.

(A) For MIPS quality measures, the entity must submit specifications including the MIPS measure IDs and specialty-specific measure sets, as applicable.

(B) For QCDR measures, the entity must submit for CMS-approval measure specifications including: Name/title of measures, NQF number (if NQF-endorsed), descriptions of the denominator, numerator, and when applicable, denominator exceptions, denominator exclusions, risk adjustment variables, and risk adjustment algorithms. In addition, no later than 15 calendar days following CMS approval of any QCDR measure specifications, the entity must publicly post the measure specifications for that QCDR measure (including the CMS-assigned QCDR measure ID) and provide CMS with a link to where this information is posted.

(ii) *QCDR measure submission requirements.* A QCDR must include the CMS-assigned QCDR measure ID when submitting data on any QCDR measure to CMS.

(iii) *QCDR measure approval criteria.* (A) QCDR measure requirements for approval are:

(*1*) QCDR measures that are beyond the measure concept phase of development.

(*2*) QCDR measures that address significant variation in performance.

(*3*) Beginning with the 2022 MIPS performance period/2024 MIPS payment year, all QCDR measures must meet face validity. To be approved for the 2023 MIPS performance period/2025 MIPS payment year, all QCDR measures must meet face validity for the initial MIPS payment year for which it is approved. For subsequent years, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

(*i*) To be included in an MVP for the 2022 MIPS performance period/2024 MIPS payment year and future years, a QCDR measure must be fully tested.

(*ii*) [Reserved]

(*4*) Beginning with the 2022 MIPS performance period/2023 MIPS payment year, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(*5*) Beginning with the 2020 MIPS performance period/2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(B) QCDR measure considerations for approval include, but are not limited to:

(*1*) Measures that are outcome-based rather than clinical process measures.

(*2*) Measures that address patient safety and adverse events.

(*3*) Measures that identify appropriate use of diagnosis and therapeutics.

(*4*) Measures that address the domain of care coordination.

(*5*) Measures that address the domain for patient and caregiver experience.

(*6*) Measures that address efficiency, cost, and resource use.

(*7*) Beginning with the 2021 performance period—

(*i*) That QCDRs link their QCDR measures as feasible to at least one cost measure, improvement activity, or an MVP at the time of self-nomination.

(*ii*) In cases where a QCDR measure does not have a clear link to a cost measure, improvement activity, or an MVP, we would consider exceptions if the potential QCDR measure otherwise meets the QCDR measure requirements and considerations.

(*8*) Beginning with the 2020 MIPS performance period/2022 MIPS payment year CMS may consider the extent to which a QCDR measure is available to MIPS eligible clinicians reporting through QCDRs other than the QCDR measure owner for purposes of MIPS. If CMS determines that a QCDR measure is not available to MIPS eligible clinicians, groups, and virtual groups reporting through other QCDRs, CMS may not approve the measure.

(*9*) Greater consideration is given to measures for which QCDRs:

(i) Conducted an environmental scan of existing QCDR measures; MIPS quality measures; quality measures retired from the legacy Physician Quality Reporting System (PQRS) program; and

(*ii*) Utilized the CMS Quality Measure Development Plan Annual Report and the Blueprint in the CMS Measures Management System to identify measurement gaps prior to measure development.

(*10*) Beginning with the 2020 MIPS performance period/2022 MIPS payment year, we place greater preference on QCDR measures that meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. Those that do not, may not continue to be approved.

(*i*) Beginning with the 2020 MIPS performance period/2022 MIPS payment year, in instances where a QCDR believes the low-reported QCDR

measure that did not meet benchmarking thresholds is still important and relevant to a specialist's practice, that the QCDR may develop and submit a QCDR measure participation plan for our consideration. This QCDR measure participation plan must include the QCDR's detailed plans and changes to encourage eligible clinicians and groups to submit data on the low-reported QCDR measure for purposes of the MIPS program.

(*ii*) [Reserved]

(C) Beginning with the 2021 MIPS performance period/2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

(iv) *QCDR measure rejection criteria.* Beginning with the 2020 MIPS performance period/2022 MIPS payment year, QCDR measure rejection considerations include, but are not limited to:

(A) QCDR measures that are duplicative or identical to other QCDR measures or MIPS quality measures that are currently in the program.

(B) QCDR measures that are duplicative or identical to MIPS quality measures that have been removed from MIPS through rulemaking.

(C) QCDR measures that are duplicative or identical to quality measures used under the legacy Physician Quality Reporting System (PQRS) program, which have been retired.

(D) QCDR measures that meet the topped out definition as described at § 414.1305.

(E) QCDR measures that are process-based, with consideration to whether the removal of the process measure impacts the number of measures available for a specific specialty.

(F) Whether the QCDR measure has potential unintended consequences to a patient's care.

(G) Considerations and evaluation of the measure's performance data, to determine whether performance variance exists.

(H) QCDR measures that split a single clinical practice or action into several QCDR measures.

(I) QCDR measures that are ''check-box'' with no actionable quality action.

(J) QCDR measures that do not meet the case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive years.

(K) QCDR measures with clinician attribution issues, where the quality action is not under the direct control of the reporting clinician.

(L) QCDR measures that focus on rare events or ''never events'' in the measurement period.

(M) QCDR does not have permission to use a QCDR measure owned by another QCDR for the applicable performance period.

(N) If a QCDR measure owner is not approved or is not in good standing, any associated QCDR measures will not be approved.

(c) *Additional requirements for Health IT vendors.* (1) Beginning with the CY 2021 MIPS performance period/2023 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:

(i) Health IT vendors that support MVPs must be able to submit data for all of the MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, virtual group, or subgroup is using CEHRT, unless:

(*1*) The third party intermediary's MIPS eligible clinicians, groups, virtual groups, or subgroups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*)(*i*) through (*iii*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(*2*) [Reserved]

(ii) Health IT vendors that do not support MVPs must be able to submit data for at least one of the MIPS performance categories described in paragraphs (c)(1)(i) of this section.

(iii) Beginning with the 2023 MIPS performance period/2025 MIPS payment year, Health IT vendors must support MVPs that are applicable to the MVP participant on whose behalf they submit MIPS data. Health IT vendors may also support the APP.

(2) [Reserved]

(d) *Additional requirements for CMS-approved survey vendors.* (1) CMS-approved survey vendors may submit data on the CAHPS for MIPS survey for the MIPS quality performance category.

(2) Entities seeking to be a CMS-approved survey vendor for any MIPS performance period must submit a survey vendor application to CMS in a form and manner specified by CMS for each MIPS performance period for which it wishes to transmit such data. The application and any supplemental information requested by CMS must be submitted by deadlines specified by CMS. For an entity to be a CMS-approved survey vendor, it must meet the following criteria:

(3) The entity must have sufficient experience, capability, and capacity to accurately report CAHPS data, including:

(i) At least 3 years of experience administering mixed-mode surveys (that is, surveys that employ multiple modes to collect date), including mail survey administration followed by survey administration via Computer Assisted Telephone Interview (CATI);

(ii) At least 3 years of experience administering surveys to a Medicare population;

(iii) At least 3 years of experience administering CAHPS surveys within the past 5 years;

(iv) Experience administering surveys in English and at least one other language for which a translation of the CAHPS for MIPS survey is available;

(v) Use equipment, software, computer programs, systems, and facilities that can verify addresses and phone numbers of sampled beneficiaries, monitor interviewers, collect data via CATI, electronically administer the survey and schedule call-backs to beneficiaries at varying times of the day and week, track fielded surveys, assign final disposition codes to reflect the outcome of data collection of each sampled case, and track cases from mail surveys through telephone follow-up activities; and

(vi) Employment of a program manager, information systems specialist, call center supervisor and mail center supervisor to administer the survey.

(4) The entity has certified that it has the ability to maintain and transmit quality data in a manner that preserves the security and integrity of the data.

(5) The entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors.

(6) The entity has submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts.

(7) The entity has agreed to participate and cooperate, and has required its subcontractors to participate and cooperate, in all oversight activities related to survey administration conducted by CMS or its contractors.

(8) The entity has sent an interim survey data file to CMS that establishes

the entity's ability to accurately report CAHPS data.

(e) *Remedial action and termination of third party intermediaries.* (1) If CMS determines that a third party intermediary has ceased to meet one or more of the applicable criteria for approval, has submitted a false certification under paragraph (a)(3) of this section, or has submitted data that are inaccurate, unusable, or otherwise compromised, CMS may take one or more of the following remedial actions after providing written notice to the third party intermediary:

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

(ii) Publicly disclose the entity's data error rate on the CMS website until the data error rate falls below 3 percent.

(2) CMS may immediately or with advance notice terminate the ability of a third party intermediary to submit MIPS data on behalf of a MIPS eligible clinician, group, or virtual group for one or more of the following reasons:

(i) CMS has grounds to impose remedial action;

(ii) CMS has not received a CAP within the specified time-period or the CAP is not accepted by CMS; or

(iii) The third party intermediary fails to correct the deficiencies or data errors by the date specified by CMS.

(3) Contains data inaccuracies affecting the third party intermediary's total clinicians may lead to remedial action/termination of the third party intermediary for future program year(s) based on CMS discretion.

(4) For purposes of paragraph (e) of this section, CMS may determine that submitted data are inaccurate, unusable, or otherwise compromised, including but not limited to, if the submitted data:

(i) Includes, without limitation, TIN/NPI mismatches, formatting issues, calculation errors, or data audit discrepancies.

(ii) [Reserved]

(f) *Auditing of entities submitting MIPS data.* Any third party intermediary must comply with the following procedures as a condition of its qualification and approval to participate in MIPS as a third party intermediary.

(1) The entity must make available to CMS the contact information of each MIPS eligible clinician or group on behalf of whom it submits data. The contact information must include, at a minimum, the MIPS eligible clinician or group's practice phone number, address, and, if available, email.

(2) The entity must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period.

(3) For the purposes of auditing, CMS may request any records or data retained for the purposes of MIPS for up to 6 years from the end of the MIPS performance period.

■ 60. Amend § 414.1405 by adding paragraphs (b)(9), (d)(7) and (g) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(9) Pursuant to the methodology established at paragraph (g) of this section, the performance threshold for the 2024 MIPS payment year is 75 points. The prior period used to determine the performance threshold is the 2019 MIPS payment year.

* * * * *

(d) * * *

(7) The additional performance threshold for the 2024 MIPS payment year is 89 points.

* * * * *

(g) *Performance threshold methodology.* For each of the 2024, 2025, and 2026 MIPS payment years, the performance threshold is the mean of the final scores for all MIPS eligible clinicians from a prior period as specified under paragraph (b) of this section.

■ 61. Amend § 414.1430 by—

■ a. Revising paragraph (a)(1)(iii); and

■ b. Adding paragraph (a)(1)(iv).

The revision and addition read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(1) * * *

(iii) 2023 and 2024: 50 percent

(iv) 2025 and later: 75 percent

* * * * *

■ 62. Amend § 414.1450 by revising paragraph (c) introductory text to read as follows:

§ 414.1450 APM incentive payment.

* * * * *

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to a solvent TIN or TINs associated with the QP, identified based on Medicare Part B claims submitted for covered professional services during the base period or payment year, according to this section. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed in paragraphs (c)(1) through (8) of this section until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM Incentive Payment. If more than one TIN is identified at a step, the payment will be proportionately divided among the TINs according to the relative total paid amounts for Part B covered professional services paid to each TIN for services provided during the base year.

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PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 63. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 64. Section 415.140 is added to subpart D to read as follows:

§ 415.140 Conditions for payment: Split (or shared) visits.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Split (or shared) visit* means an evaluation and management (E/M) visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner who are in the same group, in accordance with applicable law and regulations such that the service could be could be billed by either the physician or nonphysician practitioner if furnished independently by only one of them.

(2) *Facility setting* for purposes of this section means institutional settings in which payment for services and supplies furnished incident to a physician or practitioner's professional services is prohibited under § 410.26(b)(1).

(3) *Substantive portion* means more than half of the total time spent by the physician and nonphysician

practitioner performing the split (or shared) visit.

(b) *Conditions of payment.* For purposes of this section, the following conditions of payment apply: (1) *Substantive portion of split (or shared) visit.* In general, payment is made to the physician or nonphysician practitioner who performs the substantive portion of the split (or shared) visit.

(2) *Medical record documentation.* Documentation in the medical record must identify the physician and nonphysician practitioner who performed the visit. The individual who performed the substantive portion of the visit (and therefore bills for the visit) must sign and date the medical record.

(3) *Claim modifier.* The designated modifier must be included on the claim to identify that the service was a split (or shared) visit.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 65. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 66. Amend § 423.160 by revising paragraph (a)(5) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) Beginning on January 1, 2021, prescribers must, except in the circumstances described in paragraphs (a)(5)(i) through (iv) of this section, conduct prescribing for at least 70 percent of their Schedule II, III, IV, and V controlled substances that are Part D drugs electronically using the applicable standards in paragraph (b) of this section. Compliance actions against prescribers writing prescriptions for beneficiaries in long-term care facilities, and who do not meet the compliance threshold, will commence on or after January 1, 2025. Compliance actions against other prescribers who do not meet the compliance threshold will commence on or after January 1, 2023. Prescribers will be exempt from this requirement in the following situations:

(i) Prescriber and dispensing pharmacy are the same entity.

(ii) Prescriber who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year as determined using CMS claims data as of December 31st of the preceding year.

(iii) Prescriber with an NCPDP database address in the geographic area of an emergency or disaster declared by a federal, state or local government entity.

(iv) Prescriber has received a CMS-approved waiver because the prescriber is unable to conduct electronic prescribing of controlled substances (EPCS) due to circumstances beyond the prescriber's control.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 67. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 68. Amend § 424.205 by—

■ a. Redesignating paragraphs (b)(5) and (6) as paragraphs (b)(6) and (7), respectively; and

■ b. Adding new paragraph (b)(5);

The addition reads as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(b) * * *

(5) The Medicare provider enrollment application fee does not apply to all Medicare Diabetes Prevention Program (MDPP) suppliers that submit an enrollment application on or after January 1, 2022.

* * * * *

■ 69. Amend § 424.502 by revising the definition of ''Institutional provider'' to read as follows:

§ 424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S, or an associated internet-based PECOS enrollment application.

* * * * *

■ 70. Amend § 424.530 by revising paragraphs (a)(2) introductory text and (a)(11)(i) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(2) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

* * * * *

(11) * * * (i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

* * * * *

■ 71. Amend § 424.535 by revising paragraphs (a)(2) introductory text, (a)(8)(ii), (a)(13)(i), and (e) to read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(2) *Provider or supplier conduct.* The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, of the provider or supplier is—

* * * * *

(8) * * *

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following:

(A) The percentage of submitted claims that were denied during the period under consideration.

(B) Whether the provider or supplier has any history of final adverse actions and the nature of any such actions.

(C) The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined).

(D) Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination.

* * * * *

(13) * * *

(i) A physician or other eligible professional's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause;

* * * * *

(e) *Reversal of revocation.* If the revocation was due to adverse activity (sanction, exclusion, or felony) against the provider's or supplier's owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a federal health care program, the revocation may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that individual within 30 days of the revocation notification.

* * * * *

§ 424.545 [Amended]

■ 72. Amend § 424.545 in paragraph (b) by removing the reference ''§ 405.374'' and adding in its place the reference ''§ 424.546.''

■ 73. Add § 424.546 to read as follows:

§ 424.546 Deactivation rebuttals.

(a) *Rebuttal submittal period.* (1) If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier's billing privileges are to be or have been deactivated under § 424.540, the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS as permitted under § 424.545(b).

(2) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (a)(1) of this section.

(b) *Rebuttal requirements.* A rebuttal submitted pursuant to this section and § 424.545(b) must:

(1) Be in writing.

(2) Specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or the effective date, and the reasons for disagreement.

(3) Submit all documentation the provider or supplier wants CMS to consider in its review of the deactivation.

(4) Be submitted in the form of a letter that is signed and dated by the individual supplier (if enrolled as an individual physician or nonphysician practitioner), the authorized official or delegated official (as those terms are defined in 42 CFR 424.502), or a legal representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the provider or supplier; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the provider or supplier must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the individual supplier, the authorized official or delegated official, or a legal representative.

(c) *Waiver of rebuttal rights.* The provider's or supplier's failure to submit a rebuttal that is both timely under paragraph (a) of this section and fully compliant with all of the requirements of paragraph (b) of this section constitutes a waiver of all rebuttal rights under this section and § 424.545(b).

(d) *CMS review.* Upon receipt of a timely and compliant deactivation rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date are correct.

(e) *Imposition.* Nothing in this section or in § 424.545(b) requires CMS to delay the imposition of a deactivation pending the completion of the review described in paragraph (d) of this section.

(f) *Initial determination.* A determination made under this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 74. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 75. Amend § 425.116 by revising paragraph (c) to read as follows:

§ 425.116 Agreements with ACO participants and ACO providers/suppliers.

* * * * *

(c) *Submission of agreements.* The ACO must submit an executed ACO participant agreement for each ACO participant that it requests to add to its list of ACO participants in accordance with § 425.118. The agreements may be submitted in the form and manner set forth in § 425.204(c)(6) or as otherwise specified by CMS.

■ 76. Amend § 425.204 by—

■ a. Revising paragraphs (b), (c)(6), (f)(4)(ii)(A) and (B), (f)(4)(iii) introductory text, and (f)(4)(iii)(A); and

■ b. Adding paragraph (f)(4)(v).

The revisions and addition read as follows:

§ 425.204 Content of the application.

* * * * *

(b) *Prior participation.* Upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Medicare Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b).

(c) * * *

(6) Upon request by CMS during the application cycle or at any point during an agreement period, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. Upon such a request, the evidence to be submitted must include, without limitation, sample or form agreements and, in the case of ACO participant agreements, the first and signature page(s) of each executed ACO participant agreement. CMS may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO must certify that all of its ACO participant agreements comply with the requirements of this part.

* * * * *

(f) * * *

(4) * * *

(ii) * * *

(A) One-half percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures and the number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(B) One percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(iii) CMS recalculates the ACO's repayment mechanism amount for the second and each subsequent performance year in the agreement period in accordance with paragraph (f)(4)(ii) of this section based on the certified ACO participant list for the relevant performance year, except that the number of assigned beneficiaries used in the calculations is the number of beneficiaries assigned to the ACO at the beginning of the relevant performance year under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3)(i) (for ACOs under prospective assignment).

(A) If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least $1,000,000, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount.

* * * * *

(v)(A) An ACO that established a repayment mechanism to support its participation in a two-sided model beginning on July 1, 2019, January 1, 2020 or January 1, 2021, may elect to decrease the amount of its repayment mechanism if the repayment mechanism amount for performance year 2022, as recalculated pursuant to paragraph

(f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(B) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(v). The ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of paragraph (f) of this section.

* * * * *

■ 77. Amend § 425.312 by—
■ a. Revising paragraph (a)(2)(ii); and
■ b. Adding paragraph (a)(2)(iii).

The revision and addition read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) * * *

(ii) In the case of an ACO that has selected preliminary prospective assignment with retrospective reconciliation, by the ACO or ACO participant providing each fee-for-service beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

(iii) In the case of an ACO that has selected prospective assignment, by the ACO or ACO participant providing each prospectively assigned beneficiary with a standardized written notice prior to or at the first primary care visit of the performance year in the form and manner specified by CMS.

* * * * *

■ 78. Amend § 425.400 by—
■ a. Revising paragraph (c)(1)(v) introductory text;
■ b. Adding paragraph (c)(1)(vi); and
■ c. Revising paragraphs (c)(2)(i) introductory text, (c)(2)(i)(A)(2), and (c)(2)(ii).

The addition and revisions read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(v) For the performance year starting on January 1, 2021:

* * * * *

(vi) For the performance year starting on January 1, 2022, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(vi)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99439 (code for non-complex chronic care management).

(*9*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*11*) 99X21, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*12*) 99495 and 99496 (codes for transitional care management services).

(*13*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(*14*) 99X22, 99X23, 99X24, and 99X25 (codes for principal care management services).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 and G2252 (codes for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2212 (code for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*13*) G2214 (code for psychiatric collaborative care model).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(vi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(vi)(B) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

(2)(i) Except as otherwise specified in paragraph (c)(2)(i)(A)(*2*) of this section, when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(A) * * *

(2) 99441, 99442, and 99443 (codes for telephone evaluation and management services). These codes are used in determining beneficiary assignment as specified in paragraphs (c)(2)(i) and (ii) of this section and until they are no longer payable under Medicare fee-for-service payment policies as specified under section 1834(m) of the Act and §§ 410.78 and 414.65 of this chapter.

* * * * *

(ii) Except as otherwise specified in paragraph (c)(2)(i)(A)(2) of this section, the additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 79. Amend § 425.512 by—
■ a. Revising paragraphs (a)(2) and (3);
■ b. Redesignating paragraph (a)(4) as paragraph (a)(5);
■ c. Adding a new paragraph (a)(4);
■ d. Revising newly redesignated paragraph (a)(5);
■ e. Adding paragraph (a)(6);
■ f. Revising paragraphs (b)(2)(i) and (ii) and (b)(3)(i);
■ g. Redesignating paragraph (b)(3)(ii) as paragraph (b)(3)(iii);
■ h. Adding a new paragraph (b)(3)(ii); and

■ i. Revising newly redesignating paragraph (b)(3)(iii).

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(2) *For the first performance year of an ACO's first agreement period under the Shared Savings Program.* If the ACO reports data via the APP and meets the data completeness requirement at § 414.1340 of this chapter and the case minimum requirement at § 414.1380 of this chapter on the measures specified in this paragraph (a)(2) for the applicable performance year, the ACO will meet the quality performance standard.

(i) *For performance year 2022.* The ten CMS Web Interface measures or the three eCQM/MIPS CQM measures, and the CAHPS for MIPS survey.

(ii) *For performance year 2023.* The ten CMS Web Interface measures and at least one eCQM/MIPS CQM measure or the three eCQM/MIPS CQM measures, and the CAHPS for MIPS survey.

(iii) *For performance year 2024 and subsequent performance years.* The three eCQM/MIPS CQM measures and the CAHPS for MIPS survey.

(3) *For performance year 2021*—(i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(4) *For performance year 2022*—(i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting via the APP established under § 414.1367 of this chapter either:

(A) According to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(B) The three eCQM/MIPS CQM measures in the APP measure set, meeting the data completeness requirement at § 414.1340 of this chapter and the case minimum requirement at § 414.1380 of this chapter for all three eCQM/MIPS CQM measures, and achieving a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

(ii) If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(5) *For performance year 2023*—(i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting via the APP established under § 414.1367 of this chapter either:

(A) According to the method of submission established by CMS, including at least one eCQM/MIPS CQM measure, and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, or

(B) The three eCQM/MIPS CQM measures in the APP measure set, meeting the data completeness requirement at § 414.1340 of this chapter and the case minimum requirement at § 414.1380 of this chapter for all three eCQM/MIPS CQM measures, and achieving a quality performance score equivalent to or higher than the 30th percentile of the performance benchmark on at least one measure in the APP measure set.

(ii) If the ACO does not report at least one eCQM/MIPS CQM in the APP measure set, the ACO will not meet the quality performance standard.

(6) *For performance years 2024 and subsequent performance years.* (i) Except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the three eCQM/MIPS CQM measures and does not administer a CAHPS for MIPS survey under the APP, the ACO will not meet the quality performance standard.

(b) * * *

(2) * * *

(i) For performance years 2021 through 2023, the ACO's minimum quality performance score is set to the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring for the relevant performance year.

(ii) For performance year 2024 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(3) * * *

(i) For performance years 2021 and 2022, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

(ii) For performance year 2023, if the ACO reports quality data via the APP, including at least one eCQM/MIPS CQM measure, and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the performance year.

(iii) For performance year 2024 and subsequent performance years, if the ACO reports quality data via the APP and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year.

* * * * *

Dated: July 9, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1: MIPS Quality Measures

Note: Except as otherwise noted in this proposed rule, previously finalized measures and specialty measure sets will continue to apply for the 2022 MIPS performance period/2024 MIPS payment year and future years. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF #/eCQM NQF #.

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TABLE Group A: New Quality Measures Proposed for the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

A.1. Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.
Measure Steward:	Oregon Urology
Numerator:	Intravesical Bacillus-Calmette Guerin (BCG) instillation for initial dose or series. BCG is initiated within 6 months of the bladder cancer staging and during the measurement period.
Denominator:	All patients initially diagnosed with T1, Tis or high grade Ta non-muscle invasive bladder cancer and a qualified encounter in the measurement period.
Exclusions:	Denominator Exceptions: Unavailability of BCG Denominator Exclusions: Immunosuppressed patients, includes HIV and immunocompromised state. Immunosuppressive drug therapy. Active Tuberculosis. Mixed histology urothelial cell carcinoma including micropapillary, plasmacytoid, sarcomatoid, adenocarcinoma and squamous disease. Patients who undergo cystectomy, chemotherapy or radiation within 6 months of Bladder Cancer Staging.
Measure Type:	Process
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	eCQM Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it addresses a gap in care for patients diagnosed with bladder cancer. Treatment at this stage (non-muscle invasive) can help prevent invasion into the muscle layer which leads to potential bladder removal and additional chemotherapy and/or radiation treatment. It was reviewed by the 2016 National Quality Forum (NQF) Measure Application Partnership (MAP) with a recommendation to refine to address concerns what populations would be included or excluded from the measure. The measure was updated according to MAP feedback by redefining the eligible patient population and exclusions. The measure steward indicated that bladder cancer is ranked 10th for new cancer cases in 2020 and is the 9th leading cause of cancer death in the United States. There were an estimated 81,400 new cases in 2020 and 17,980 estimated deaths in 2020. Early detection (discovery of cancer in situ or localized to the primary site) is found in 85 percent of the patients, and with these there is a 5-year survival rate of 95.8 percent for in situ and 69.2 percent for localized. National Comprehensive Cancer Network (NCCN) Guidelines for Bladder Cancer (version 6.2020) defines intravesical Bacillus-Calmette-Guerin (BCG) as Category 1 Treatment for Ta - high grade, T1 and Tis non-muscle invasive bladder cancer. Most public data reflect prophylactic or adjuvant use of intravesical therapy with the goal of preventing recurrence or delaying progression to a higher grade or stage. Intravesical BCG has been shown to be an effective prophylaxis to prevent bladder cancer recurrences following transurethral resection of a bladder tumor (TURBT). The NCCN Bladder Cancer Panel Members recommend BCG as the preferred option over Mitomycin C for adjuvant treatment of high-grade lesions (Ta). BCG is also standard therapy for Primary Tis. Most T1 lesions are high risk and are similarly treated with adjuvant intravesical therapy with BCG being a Category 1 recommendation. (NCCN guidelines 6.2020). Based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical practice. Note: Refer to https://ecqi.healthit.gov/ecqm/ep/2022/cms646v2 for information on this measure.

A.2. Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.
Denominator:	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month under the care of the same practitioner or group partner.
Exclusions:	Exclusions that are implicit in the denominator definition include: • Pediatric patients (<18 years old). • Patients on Peritoneal Dialysis for any portion of the reporting month. • Patient-months where there are more than one MCP provider listed for the month. In addition, patients with a catheter that have limited life expectancy, as defined by the following criteria are excluded: • Patients under hospice care in the current reporting month. • Patients with metastatic cancer in the past 12 months. • Patients with end stage liver disease in the past 12 months. • Patients with coma or anoxic brain injury in the past 12 months
Measure Type:	Intermediate Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure because it represents an intermediate outcome for maintenance hemodialysis patients and may incentivize clinicians to evaluate their vascular access with potential to reduce infection, mortality, and hospitalization rates. Long-term catheter use is associated with higher mortality rate than use of an arteriovenous fistula. The measure was evaluated by the MAP and it was conditionally supported pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. The measure steward indicated, per their analysis of Consolidated Renal Operations in a Web enabled Network (CROWNWeb) data from January 2016 - December 2016, that the physician-level mean percentage of patient-months with a long-term catheter was 9.7 percent (SD=9.0 percent). Distribution: Min=0 percent, 1st quartile=4.5 percent, median=8.3 percent, 3rd quartile=12.7 percent, Max=100 percent. Reliability testing included 7,921 – 8,508 clinicians per month with moderate inter-unit reliability of 0.602 indicating that 60.2 percent of the variation in the annual long-term catheter rate can be attributed to between-practitioner differences in performance (signal) and about 39.8 percent to the within-practitioner variation (noise). Based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical practice. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

A.3. Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive stakeholder engagement and comprehensive reviews of the literature.
Measure Steward:	The American Board of Family Medicine
Numerator:	The target population is all active patients in a practice during the performance reporting period. A patient is defined as active if the patient has had a documented interaction with the practice within 12 months of their birth month within the measurement period. The PCPCM PROM is the same for all patients, regardless of age. Because the PCPCM PROM applies to all patients and is not particular to a clinical encounter, it is administered once a year to each patient during their birth month. The target population is defined the same, regardless of unit of analysis (clinician, practice, or system). The numerator is the sum of all PCPCM PROM scores for active patients. 1. My practice makes it easy for me to get care. 2. My practice is able to provide most of my care. 3. In caring for me, my doctor considers all the factors that affect my health. 4. My practice coordinates the care I get from multiple places. 5. My doctor or practice knows me as a person. 6. My doctor and I have been through a lot together. 7. My doctor or practice stands up for me. 8. The care I get takes into account knowledge of my family. 9. The care I get in this practice is informed by knowledge of my community. 10. Over time, my practice helps me to stay healthy. 11. Over time, my practice helps me to meet my goals.
Denominator:	The denominator is the total number of complete PCPCM PROM instruments received in the reporting period. A completed PROM instrument is defined as a PROM instrument for which the patient has responded to at least 8 of 11 items. The target population is all active patients in a practice during the performance reporting period. A patient is defined as active if the patient has had a documented interaction with the practice within 12 months of their birth month during the measurement period. The PCPCM PROM is the same for all patients, regardless of age. Because the PCPCM PROM applies to all patients and is not particular to a clinical encounter, it is administered once a year to each patient during their birth month. The target population is defined the same, regardless of unit of analysis (clinician, practice, or system).
Exclusions:	None
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Measure Domain:	Person and Caregiver-centered Experience and Outcomes (section 1848(s)(1)(B)(iv) of the Act)
High Priority Measure:	Yes
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period::	For each MIPS eligible clinician, group, subgroup*, virtual group, and APM Entity, a minimum of 30 PCPCM PROM instruments per clinician are needed for submission of this measure. All valid survey results (as defined in the specification) should be included in the aggregate score. For MIPS eligible groups, subgroups*, virtual groups, and APM Entities with 5 or more clinicians, a minimum of 150 PCPCM PROM instruments per TIN for each site/location associated with the clinicians part of the group, subgroups, virtual groups, and APM Entities are needed for submission of this measure. For TINs with a composition of multiple specialty practices at one site/location, a minimum of 150 PCPCM PROM instruments per specialty practice within a TIN are needed for submission of this measure. If the MIPS eligible group, subgroup*, virtual group, and APM Entity with 5 or more clinicians encompasses multiple sites/locations, each site/location would need to meet the PCPCM PROM instruments requirements as stated. *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We are proposing this measure because assessment of patient experience of care is a critical element of quality care and captures the voice of the patient which is an important component of delivering high-value primary care. There are currently a limited number of patient experience measures within the MIPS quality measure set. The original measure was evaluated by the NQF MAP and received conditional support pending NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. Based on research of the available information presented to the MAP, evidence demonstrates a strong connection between patient experience of care and traditional health care outcomes, such as improved intermediate outcomes, greater adherence to recommended treatment, and reduced use of health care services. This measure addresses the Meaningful Measurement Area of Patient's Experience of Care and the MIPS high-priority category of Outcomes. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

A.4. Risk-Standardized Acute Unplanned Cardiovascular-Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System

Category	Description
NQF # / eCQM NQF #:	NQF # 3612
Quality #:	TBD
Description:	Annual risk-standardized rate of acute, unplanned cardiovascular-related admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with heart failure (HF) or cardiomyopathy.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is the number of acute cardiovascular-related admissions per 100 person-years at risk for admission during the measurement year. Time at risk is calculated as the number of days a patient is alive, from the start of the measurement period or first visit, until heart transplantation, LVAD implantation, or home inotropic therapy; enrollment in hospice; death; or the end of the measurement period. Time not considered at risk and excluded: Days spent in a hospital, SNF, or acute rehabilitation facility; 10 days following discharge from a hospital, SNF, or acute rehabilitation facility; and Time during and after LVAD implantation, home inotropic therapy, or heart transplantation. Acute cardiovascular-related admissions are defined using individual ICD-10-CM codes and the Agency for Healthcare Research and Quality's (AHRQ) Clinical Classification Software (CCS) diagnosis categories, which group clinically similar codes together. AHRQ CCS diagnosis categories used to define outcome: 55: Fluid and electrolyte disorders; 96: Heart valve disorders; 97: Peri-; endo-; and myocarditis; cardiomyopathy (except that caused by tuberculosis or sexually transmitted disease); 98: Essential hypertension; 100: Acute myocardial infarction; 102: Nonspecific chest pain; 104: Other and ill-defined heart disease; 105: Conduction disorders; 106: Cardiac dysrhythmias; 107: Cardiac arrest and ventricular fibrillation; 108: Congestive heart failure; non-hypertensive; 110: Occlusion or stenosis of precerebral arteries; 112: Transient cerebral ischemia; 115: Aortic; peripheral; and visceral artery aneurysms; 116: Aortic and peripheral arterial embolism or thrombosis; 157: Acute and unspecified renal failure; 245: Syncope. Subsets of the following AHRQ CCS diagnosis categories used to define outcome: 99: Hypertension with complications and secondary hypertension; 101: Coronary atherosclerosis and other heart disease; 103: Pulmonary heart disease; 109: Acute cerebrovascular disease; 114: Peripheral and visceral atherosclerosis; 117: Other circulatory disease; 130: Pleurisy; pneumothorax; pulmonary collapse; 131: Respiratory failure; insufficiency; arrest (adult); 133: Other lower respiratory disease; 237: Complication of device; implant or graft. The measure has several outcome exclusions: Planned admissions; Admissions from a skilled nursing facility (SNF) or acute rehab facility; Admissions within 10 days of discharge from a hospital, SNF, or acute rehab; Admissions after patient has entered hospice; Admissions before first visit to provider if no prior year visit; Admissions at time of or following: LVAD implantation, home inotropic therapy, or heart transplant.
Denominator:	The measure includes Medicare FFS beneficiaries >65 years of age with at least one inpatient principal diagnosis for heart failure/cardiomyopathy, or at least two outpatient or inpatient heart failure/cardiomyopathy diagnoses in any coding position (e.g., primary or secondary position) within the two years prior to the measurement year. • Beneficiaries must be enrolled full-time in Medicare Part A and B during the year prior to measurement and during the measurement period. Additionally, the cohort excludes: Patients with internalized left ventricular assist devices (LVADs); Patients with heart transplants; Patients on home inotropic therapy; Patients on hospice for any reason; Patients with end-stage renal disease (ESRD) – defined as chronic kidney disease stage 5 or on dialysis. Provider types included for measurement (vetted by TEP and Clinician Committee): Primary care providers (PCPs): CMS designates PCPs as physicians who practice internal medicine, family medicine, general medicine, or geriatric medicine, and non-physician providers, including nurse practitioners, certified clinical nurse specialists, and physician assistants; Cardiologists: Cardiologists are covered by the measure because they provide overall coordination of care for patients with HF and manage the conditions that put HF patients at risk for admission due to acute cardiovascular-related conditions. Outcome attribution: We begin by assigning each patient to the clinician most responsible for the patient's care, based on the pattern of outpatient visits with PCPs and relevant specialists. The patient can be assigned to a PCP, a cardiologist, or can be left unassigned. A patient who is eligible for attribution is assigned to a cardiologist if they have 2 or more visits with a single cardiologist, regardless of how many visits that patient has with a PCP. There are two scenarios where a patient can be assigned to a PCP. • First, if the patient has seen the PCP at least once but has no visits with a cardiologist, the patient is assigned to the PCP. • Second, if the patient has seen the PCP more than 2 or more times and has only one visit with a cardiologist, the patient is assigned to the PCP. If the patient has 1 visit each with a cardiologist and a PCP, the patient is assigned to the cardiologist. If the patient has 1 visit with a cardiologist and no visit with a PCP, the patient is assigned to the cardiologist. • Finally, the patient will be unassigned if they had no visits with a PCP or cardiologist. Patients are then assigned at the Taxpayer Identification Number (TIN) level, which includes solo clinicians and groups of clinicians who have chosen to report their quality under a common TIN. Patients "follow" their clinician to the TIN designated by the clinician (i.e. they are assigned to their clinician's TIN). Patients unassigned at the individual clinician-level, therefore, continue to be unassigned at the TIN level.
Exclusions:	Numerator Exclusions: The measure does not include the following types of admissions in the outcome because they do not reflect the quality of care provided by ambulatory care clinicians who are managing the care of HF patients: Planned admissions (utilizes the adapted planned admission algorithm (PAA) to identify and exclude admissions that are planned); Admissions that likely do not reflect the quality of heart failure management provided by ambulatory clinicians including: Admissions that occur within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility ("10-day buffer period"); Admissions that occur while patients are enrolled in Medicare's hospice benefit; Admissions that occur prior to the first visit with the assigned clinician. Admissions on the date or after any of the following: LVAD implantation, home inotropic therapy, or heart transplant (censored at the time of transition to advanced care).

Category	Description
	Denominator Exclusions: The measure excludes: 1. Patients without continuous enrollment in Medicare Parts A and B for the duration of the measurement period. 2. Patients who (or until death), were ever in hospice during the year prior to the measurement year or in hospice at the start of the measurement period. 3. Patients who have had no Evaluation & Management (E&M) visits to a MIPS eligible clinician. 4.. Patients who have had a heart transplant, been on home inotropic therapy, or who have had a left ventricular assist device (LVAD) placed.
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	Administrative Claims
Measure-Specific Case Minimum/Performance Period:	MIPS eligible clinicians, groups, subgroups*, virtual groups, and APM Entities / 21 case minimum / 1 year performance period (January 1st – December 31st) *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We are proposing this administrative claims outcome measure as HF is a leading cause of hospitalization in the United States and a major source of disease burden among the elderly population. Approximately 5.7 million adults in the United States have HF, costing the United States $30.7 billion each year, which includes the cost of health care services, medications for treatment, and missed days of work.[1] The toll on patients is also great, with high rates of hospitalization and mortality; nearly half of people with HF die within 5 years of their diagnosis.[2] Patients with chronic HF are vulnerable to a range of complications that may put them at risk for hospitalization, including worsening of HF symptoms and destabilization due to other conditions, such as respiratory disease or infection. To expand the list of available reporting options for clinicians, we are proposing this HF measure for use in the MIPS program, as it is an administrative claims measure, which has no reporting burden. Another version of this measure specified for Accountable Care Organizations (ACOs), "Risk-standardized Acute Admission Rates for Patients with Heart Failure" (ACO-37, NQF ID 2886) was previously used in the CMS Medicare Shared Savings Program, initially for accountability and currently as an informational measure. We used the ACO-37 measure in the Shared Savings Program ACO quality measure set until 2019 and since 2019 has provided ACOs with their performance on the measure in quarterly claims-based reports for ACOs to use in quality improvement activities. The HF measure was evaluated by the NQF MAP who did not recommend for rulemaking with potential for mitigation siting NQF endorsement and an analysis of the appropriateness of the risk adjustment for clinicians with higher caseloads of patients with more complicated or severe heart failure. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. While the measure raises concerns that the risk adjustment may not adequately account for advanced heart failure stages, based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical practice and has provided valuable information for other programs. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

[1] Heidenreich Paul A, Trogdon Justin G, Khavjou Olga A, et al. Forecasting the Future of Cardiovascular Disease in the United States. Circulation. 2011;123(8):933-944.

[2] Mozaffarian D, Benjamin Emelia J, Go Alan S, et al. Heart Disease and Stroke Statistics—2016 Update. Circulation. 2016;133(4):e38-e360.

A.5. Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions[267]

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Annual risk-standardized rate of acute, unplanned hospital admissions among Medicare Fee-for-Service (FFS) patients aged 65 years and older with multiple chronic conditions (MCCs).
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	"The outcome for this measure is the number of acute, unplanned hospital admissions per 100 person-years at risk for admission during the measurement period. Time Period The outcome includes inpatient admissions to an acute care hospital during the measurement year. Excluded Admissions This measure does not include the following types of admissions in the outcome because they do not reflect the quality of care provided by ambulatory care clinicians who are managing the care of MCC patients: 1. Planned hospital admissions. 2. Admissions that occur directly from a skilled nursing facility (SNF) or acute rehabilitation facility. 3. Admissions that occur within a 10-day "buffer period" of time after discharge from a hospital, SNF, or acute rehabilitation facility. 4. Admissions that occur after the patient has entered hospice. 5. Admissions related to complications from procedures or surgeries. 6. Admissions related to accidents or injuries. 7. Admissions that occur prior to the first visit with the assigned clinician or clinician group. To identify planned admissions, the measure adopted an algorithm CORE previously developed for CMS's hospital readmission measures, CMS's Planned Readmission Algorithm Version 4.0. [1,2] In brief, the algorithm uses the procedure codes and principal discharge diagnosis code on each hospital claim to identify planned admissions. A few specific, limited types of care are always considered planned (for example, major organ transplant, rehabilitation, and maintenance chemotherapy). Otherwise, a planned admission is defined as a non-acute admission for a scheduled procedure (for example, total hip replacement or cholecystectomy). Admissions for an acute illness are never considered planned. To identify complications of procedures or surgeries, we use the Agency for Healthcare Research and Quality's (AHRQ's) Clinical Classifications Software (CCS), which clusters diagnoses into clinically meaningful categories using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) or International Classification of Diseases, Tenth Revision, and Clinical Modification (ICD-10-CM) codes. We exclude the following 23 CCS categories. 1. 145: Intestinal obstruction without hernia 2. 237: Complication of device; implant or graft 3. 238: Complications of surgical procedures or medical care 4. 257: Other aftercare b) Accidents or injuries 5. 2601 E Codes: Cut/pierce 6. 2602 E Codes: Drowning/submersion 7. 2604 E Codes: Fire/burn 8. 2605 E Codes: Firearm 9. 2606 E Codes: Machinery 10. 2607 E Codes: Motor vehicle traffic (MVT) 11. 2608 E Codes: Pedal cyclist; not MVT 12. 2609 E Codes: Pedestrian; not MVT 13. 2610 E Codes: Transport; not MVT 14. 2611 E Codes: Natural/environment 15. 2612 E Codes: Overexertion 16. 2613 E Codes: Poisoning 17. 2614 E Codes: Struck by; against 18. 2615 E Codes: Suffocation 19. 2616 E Codes: Adverse effects of medical care 20. 2618 E Codes: Other specified and classifiable 21. 2619 E Codes: Other specified; NEC 22. 2620 E Codes: Unspecified 23. 2621 E Codes: Place of occurrence Person-time at risk Persons are considered at risk for hospital admission if they are alive, enrolled in Medicare FFS, and not in the hospital during the measurement period. In addition to time spent in the hospital, we also exclude from at-risk time: 1) time spent in a SNF or acute rehabilitation facility; 2) the time within 10 days following discharge from a hospital, SNF, or acute rehabilitation facility; and 3) time after entering hospice care. Citations

[267] This proposed quality measure is a Population Health measure.

Category	Description
	1. Yale New Haven Health Services Corporation – Center for Outcomes Research & Evaluation (YNHHSC/CORE). 2018 All-Cause Hospital Wide Measure Updates and Specifications Report - Hospital-Level 30-Day Risk-Standardized Readmission Measure – Version 7.0. Centers for Medicare & Medicaid Services; March 2018. 2. Horwitz L, Grady J, Cohen D, et al. Development and validation of an algorithm to identify planned readmissions from claims data. Journal of Hospital Medicine. October 2015;10(10):670-677."
Denominator:	"Patients included in the measure (target patient population) The cohort is comprised of patients whose combinations of chronic conditions put them at high risk of admission and whose admission rates could be lowered through better care. This definition reflects NQF's "Multiple Chronic Conditions Measurement Framework," which defines patients with MCCs as people "having two or more concurrent chronic conditions that…act together to significantly increase the complexity of management, and affect functional roles and health outcomes, compromise life expectancy, or hinder self-management." [1] The specific inclusion criteria are as follows. • Patient is alive at the start of the measurement period and has two or more of nine chronic disease groups in the year prior to the measurement period. Chronic conditions, except for diabetes, are defined using CMS's Chronic Conditions Data Warehouse (CCW). For diabetes, we used the diabetes cohort definition from the Accountable Care Organization (ACO) diabetes admission measure developed by CORE (v2018a ACO-36) as opposed to the definition used in CCW; CCW includes diagnoses for secondary and drug-induced diabetic conditions that are not the focus of the MIPS MCC admission measure. 1. Acute myocardial infarction (AMI), 2. Alzheimer's disease and related disorders or senile dementia, 3. Atrial fibrillation, 4. Chronic kidney disease (CKD), 5. Chronic obstructive pulmonary disease (COPD) or asthma, 6. Depression, 7. Diabetes, 8. Heart failure, and 9. Stroke or transient ischemic attack (TIA). • Patient is aged ≥65 years at the start of the year prior to the measurement period. • Patient is a Medicare FFS beneficiary with continuous enrollment in Medicare Parts A and B during the year prior to the measurement period. Provider types included for measurement • Primary care providers (PCPs): CMS designates PCPs as physicians who practice internal medicine, family medicine, general medicine, or geriatric medicine, and non-physician providers, including nurse practitioners, certified clinical nurse specialists, and physician assistants. • Relevant specialists: Specialists covered by the measure are limited to those who provide overall coordination of care for patients with MCCs and who manage the chronic diseases that put the MCC patients in the measure at risk of admission. These specialists were chosen with input from our Technical Expert Panel (TEP) and include cardiologists, pulmonologists, nephrologists, neurologists, endocrinologists, and hematologists/oncologists. Outcome attribution We begin by assigning each patient to the clinician most responsible for the patient's care, based on the pattern of outpatient visits with PCPs and relevant specialists. The patient can be assigned to a PCP, a relevant specialist, or can be left unassigned. • A patient who is eligible for attribution can be assigned to a relevant specialist only if the specialist has been identified as "dominant". A specialist is considered "dominant" if they have two or more visits with the patient, as well as at least two more visits than any primary care provider or other relevant specialist. • There are two scenarios where a patient can be assigned to a PCP. First, the patient must have seen at least one PCP. The patient will then be assigned to the PCP with the highest number of visits if there are no relevant specialists who are considered "dominant". Second, if the patient has had more than one visit with a relevant specialist, no "dominant" specialist has been identified, and has two or more visits with a PCP, they will be assigned to that PCP. • Finally, the patient will be unassigned if they only saw non-relevant specialists, if the patient has not seen a PCP and no "dominant" specialist can be identified, or if the patient has not had more than one visit with any individual PCP. Patients are then assigned at the Taxpayer Identification Number (TIN) level, which includes solo clinicians and groups of clinicians who have chosen to report their quality under a common TIN. • Patients "follow" their clinician to the TIN designated by the clinician (i.e. they are assigned to their clinician's TIN). Patients unassigned at the individual clinician-level, therefore, continue to be unassigned at the TIN level. Citations 1. National Quality Forum. Multiple Chronic Conditions Measurement Framework. http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=71227. Accessed February 20, 2019."
Exclusions:	Denominator Exclusions: "The cohort excludes the following patients: 1) Patients without continuous enrollment in Medicare Part A or B during the measurement period. 2) Patients who were in hospice at any time during the year prior to the measurement year or at the start of the measurement year. 3) Patients who had no Evaluation & Management (E&M) visits to a MIPS-eligible clinician type. 4) Patients assigned to clinician who achieve QP status and therefore do not participate in MIPS. 5) Patients attributed to hematologists and oncologists. 6) Patients not at risk for hospitalization during the measurement year." Note: Exclusions 1-3 are applied prior to attribution, while exclusions 4-6 are applied after the attribution algorithm is run.

Category	Description
Measure Type:	Outcome
Measure Domain:	Effective Clinical Care (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	Yes
Collection Type:	Administrative Claims
Measure-Specific Case Minimum/Performance Period:	MIPS eligible groups, subgroups*, virtual groups, and APM Entities with at least 16 clinicians / 18 case minimum / 1 year performance period (January 1st – December 31st) *Subgroups are only available through MVP reporting. All measure-specific criteria must be met by the subgroup.
Rationale:	We are proposing this risk-standardized hospital admission rate administrative claims outcome measure as patients with MCCs are at high risk for hospital admission, often for potentially preventable causes, such as exacerbation of pulmonary disease. Evidence from several Medicare demonstration projects suggests that care coordination results in decreased hospital admission rates among high-risk patients. In addition, studies have shown that the types of ambulatory care clinicians this measure targets (for example, primary care providers and specialists caring for patients with MCCs) can influence admission rates through team-based and enhanced access to care, found specifically in the patient-centered medical home (PCMH) model of interventions, and broadly through increased primary care supply and continuity of care. To expand the list of available reporting options for clinicians, we are proposing the MCC measure for use in the MIPS program, as it is an administrative claims measure, which has no reporting burden. This measure was evaluated by the NQF MAP in 2019, who did not support for rulemaking with potential for mitigation, including applying the measure to clinician groups, not to individual clinicians, a higher reliability threshold (e.g., 0.7; 3), consideration of patient preference and selection as a method of attribution and NQF endorsement. While we agree with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required by section 1848(q)(2)(D)(v) of the Act. This measure has been submitted for endorsement as part of the fall 2020 NQF cycle. The measure developer indicated the measure will be used for clinician group reporting with a mean reliability score for groups of >15 clinicians with at least 18 MCC patients at 0.873. While the developer indicated that the patient attestation is not yet available for testing, based on research of the available information presented at the MAP, we believe the measure is evidence-based and represents an important clinical practice addressing a large Medicare patient population. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

TABLE Group AA: COVID-19 Vaccination by Clinicians

In addition to the new quality measures in Table Group A, we are seeking comment on one quality measure for potential future inclusion within MIPS. We refer readers to section IV.A.3.d.(1)(f) of this proposed rule for our request for information pertaining to the COVID-19 Vaccination by Clinicians measure specifications.

AA.1. SARS-CoV-2 Vaccination by Clinicians

Category	Description
NQF # / eCQM NQF #:	N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older seen for a visit during the measurement period who have ever received or reported having ever received a SARS-CoV-2 vaccination dose OR who have ever received or reported having ever received a full SARS-CoV-2 vaccination course.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	Patients who have ever received or reported having ever received a SARS-CoV-2 vaccination dose OR who have ever received or reported having ever received a full SARS-CoV-2 vaccination course.
Denominator:	All patients aged 18 years and older seen for a visit during the measurement period.
Exclusions:	Patient received hospice services any time during the measurement period. Exceptions: 1. SARS-CoV-2 vaccine dose or full SARS-CoV-2 vaccination course was not administered, as documented by clinician, due to patient contraindication. 2. SARS-CoV-2 vaccine dose or full SARS-CoV-2 vaccination course was not administered, as documented by clinician, due to patient refusal. 3. SARS-CoV-2 vaccine dose or full SARS-CoV-2 vaccination course was not administered, as documented by clinician, due to vaccine being unavailable.
Measure Type:	Process
Measure Domain:	Community/Population Health (section 1848(s)(1)(B)(i) of the Act)
High Priority Measure:	No
Collection Type:	MIPS CQMs Specifications
Measure-Specific Case Minimum/Performance Period:	N/A for this measure
Rationale:	We are proposing this measure for comment as it represents a promising effort to advance measurement of vaccination for an evolving pandemic. On December 19, 2020, the Advisory Committee on Immunization Practice (ACIP) made an interim recommendation on the use of the Moderna COVID-19 vaccine for people ages 18 and older. Earlier that month, on December 12, ACIP also granted use of the Pfizer-BioNTech COVID-19 vaccine for people ages 16 and older, as an interim recommendation. The benefits of both vaccines were classified as high certainty (Type 1) based on the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) evidence assessment. On February 28, 2021 ACIP issued an interim recommendation for use of the Janssen COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19. The benefit for this single dose vaccine was classified as moderate certainty (Type 2) based on the GRADE evidence assessment. Future versions of the measure will be updated as more evidence and guidelines emerge. This measure would add value to the MIPS quality measure set by providing visibility into an important intervention to limit COVID-19 infections. In addition, collecting information on severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination coverage and providing feedback to clinicians, will facilitate performance benchmarking and drive quality improvement. Vaccination coverage will reduce transmission of COVID-19 and the associated mortality and morbidity. This measure was reviewed by the NQF MAP, who recommended conditional support for future rulemaking contingent on us bringing the measure back to MAP once the specifications are further refined. We are considering an expedited process for this measure recognizing the importance of a vaccine during a public health emergency and are exploring the inclusion of pediatric hospitals within this COVID-19 vaccination measure. Based on research of the available information presented to the MAP, we believe the measure is evidence-based and represents an important clinical topic. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.

TABLE Group B: New Specialty Measures Set Proposed for Addition and Modifications to Previously Finalized Specialty Measures Sets Proposed for the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

We are proposing to add one new specialty measures set: Certified Nurse Midwife. This set is proposed to be added based in part on the proposed expanded definition of the MIPS eligible clinician to include certified nurse midwife under Section IV.A.3.a. of this proposed rule. Note: Clinical Social Work is also being proposed as a MIPS eligible clinician type under Section IV.A.3.a. of this proposed rule. See Table B.7 for the proposed changes to the previously finalized Clinical Social Work specialty set.

We are proposing to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, proposed the addition of new measures for inclusion in MIPS, and considered the feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent the regulatory definition of high priority measures. In addition, electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table Group B as follows: NQF # / eCQM NQF #.

The definition of high priority at §414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

It should be noted that in the 2021 PFS final rule (85 FR 84870), the CMS Web Interface measures as a collection type would sunset starting with the CY 2022 MIPS performance period; however, in section IV.A.3.d.(1)(d) of this proposed rule, we are proposing to extend the availability of the CMS Web Interface measures as a collection type for the 2022 MIPS performance period and sunset the CMS Web Interface measures starting with the CY 2023 MIPS performance period. Therefore, we are proposing to modify the CMS Web Interface Measure Specifications collection type as outlined in the applicable measures within the B tables. In conjunction with seeking public comment on the proposal to extend the availability of the CMS Web Interface measures as a collection type, we are seeking public comment on the modifications proposed for the CMS Web Interface Measure Specifications collection type given that the CMS Web Interface Measure Specifications collection type has generally remained the same for three consecutive (CY 2019, CY 2020, and CY 2021) MIPS performance periods.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Allergy/Immunology specialty set.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of IIIV with a IIIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population IIealth	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ALLERGY/IMMUNOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma**: The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Anesthesiology specialty set.

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES IN THE ANESTHESIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	404	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Anesthesiology Smoking Abstinence:** The percentage of current smokers who abstain from cigarettes prior to anesthesia on the day of elective surgery or procedure.	American Society of Anesthesiologists
! (Outcome)	N/A / N/A	424	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, who undergo surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer for whom at least one body temperature greater than or equal to 35.5 degrees Celsius (or 95.9 degrees Fahrenheit) was achieved within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	430	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	463	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics):** Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.	American Society of Anesthesiologists
! (Opioid)	N/A / N/A	477	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Multimodal Pain Management:** Percentage of patients, aged 18 years and older, undergoing selected surgical procedures that were managed with multimodal pain medicine.	American Society of Anesthesiologists

B.2. Anesthesiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ANESTHESIOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Audiology specialty set.

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
* ! (Patient Safety)	0101 / N/A	318	CMS139v 10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.3. Audiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE AUDIOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Cardiology specialty set.

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Inter-mediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communicatio n and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
§ ! (Efficiency)	N/A / N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation
! (Efficiency)	N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged > 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.4a. Cardiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE CARDIOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Electrophysiology Cardiac Specialist specialty set.

B.4b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, we are soliciting comment on applicable measures for a Certified Nurse Midwife specialty set, which takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. CMS may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures because certified nurse midwife is being proposed for inclusion in the definition of a MIPS eligible clinician type. We request comment on the measures available in the Certified Nurse Midwife specialty set.

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
* ! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.

B.5. Certified Nurse Midwife

MEASURES PROPOSED FOR **ADDITION** TO THE CERTIFIED NURSE MIDWIFE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Inclusion**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention	We propose to include this measure in the Certified Nurse Midwife specialty set as it is clinically relevant to this clinician type.

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Chiropractic Medicine specialty set.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.6. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Clinical Social Work specialty set.

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology

B.7. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association /American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v10	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dentistry specialty set.

B.8. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v10	eCQM Specifications	Outcome	Community /Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v11	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Dermatology specialty set.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.9. Dermatology

MEASURES PROPOSED FOR **ADDITION** TO THE DERMATOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A/ N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology	We propose to include this measure in the Dermatology specialty set as it is clinically relevant to this clinician type. Previous stakeholder feedback resulted in an expanded list of acceptable medications, proposed in Table D.20, which now cover the broader dermatological patient population. With this expansion, and the clinical relevance to this clinician type, we propose to add to the Dermatology specialty set.

B.9. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE DERMATOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Diagnostic Radiology specialty set.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
! (Care Coordination)	N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ National Committee for Quality Assurance

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DIAGNOSTIC RADIOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0507/ N/A	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0509/ N/A	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Emergency Medicine specialty set.

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	N/A / 0104e	107	CMS161v10	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
*	N/A / N/A	254	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.11. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Endocrinology specialty set.

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CM Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.12. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS645v5	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Family Medicine specialty set.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (IIbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
*	N/A / N/A	009	CMS128v10	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
	N/A / 0104e	107	CMS161v10	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A / N/A	305	CMS137v10	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v10	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And • Most recent tobacco status is Tobacco Free -- And • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And • Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16 20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v4	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.13. Family Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive stakeholder engagement and comprehensive reviews of the literature.	The American Board of Family Medicine	We propose to include this measure in the Family Medicine specialty set as it is clinically relevant to this clinician type. This measure assesses the element of patient experience in care quality within the broad scope of primary care. Capturing the voice of the patient is an important component of delivering high-value primary care which is a focus of family medicine. Therefore, given the expansive purview of this specialty and applicability of this component in improving patient care, we propose the inclusion of this measure within the Family Medicine specialty set. See Table A.3 for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.13. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Gastroenterology specialty set.

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A/ N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
§ ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association

B.14. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GASTROENTEROLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	317	CMS22v10	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.15 General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed General Surgery specialty set.

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.15. General Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GENERAL SURGERY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Geriatrics specialty set.

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149 v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* § ! (Outcome)	0710 / 0710e	370	CMS159 v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (−/- 60 days) after an index event date.	Minnesota Community Measurement

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
* ! (Outcome)	N/A / N/A	476	CMS771 v3	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.16. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GERIATRICS SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Hospitalists specialty set.

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists

B.17. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.18. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Internal Medicine specialty set.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v10	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology -Head and Neck Surgery

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / 0104e	107	CMS161v10	eCQM Measure Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Opioid)	N/A / N/A	305	CMS137v10	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v10	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v11	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* § ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v4	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.19. Internal Medicine

MEASURES PROPOSED FOR **ADDITION** TO THE INTERNAL MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-centered Experience and Outcomes	**Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM):** The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM PROM (a comprehensive and parsimonious set of 11 patient-reported items) to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the provider or practice. Patients identify the PCPCM PROM as meaningful and able to communicate the quality of their care to their clinicians and/or care team. The items within the PCPCM PROM are based on extensive stakeholder engagement and comprehensive reviews of the literature.	The American Board of Family Medicine	We propose to include this measure in the Internal Medicine specialty set as it is clinically relevant to this clinician type. This measure assesses the element of patient experience in care quality within the broad scope of primary care. Capturing the voice of the patient is an important component of delivering high-value primary care which is a focus of internal medicine. Therefore, given the expansive purview of this specialty and applicability of this component in improving patient care, we propose the inclusion of this measure within the Internal Medicine specialty set. See Table A.3 for rationale.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented**: Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.19. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Interventional Radiology specialty set.

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	MIPS CQMs Specifications, eCQM Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology

B.20. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.21. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Mental/Behavioral Health specialty set.

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	009	CMS128v10	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
	N/A/ / 0104e	107	CMS161v10	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* §	N/A / N/A	366	CMS136v11	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
! (Patient Safety)	N/A / 1365e	382	CMS177v10	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* § ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication / Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.21. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE MENTAL/BEHAVIORAL HEALTH SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented**: Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal from this specialty set beginning with the 2024 MIPS payment year. Specialty specific coding was not added to this quality measure for the 2022 performance period. In addition, the measure's limited existing mental/behavioral health coding has resulted in limited submissions of this measure historically. Therefore, this measure has minimal eligibility for this clinician type, and we propose to remove it.

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nephrology specialty set.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association

B.22. Nephrology

MEASURES PROPOSED FOR **ADDITION** TO THE NEPHROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A/ N/A	TBD	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate**: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access attributable to an individual practitioner or group practice.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Nephrology specialty set as it is clinically relevant to this clinician type. Given the high rates that patients with kidney diseases are treated and managed within this specialty, we recommend the inclusion of this measure in the Nephrology specialty set. See Table A.2 for rationale.

B.22. Nephrology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEPHROLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurology specialty set.

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.23. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEUROLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/N/A	317	CMS22 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented**: Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Neurosurgical specialty set.

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 1 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
* ! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement

B.24. Neurosurgical

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NEUROSURGICAL SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Nutrition/Dietician specialty set.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	239	CMS155v10	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.25. Nutrition/Dietician

MEASURES PROPOSED FOR **ADDITION** TO THE NUTRITION/DIETICIAN SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0417/ N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation**: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association	We propose to include this measure in the Nutrition/ Dietician specialty set as it is clinically relevant to this clinician type. Based on previous stakeholder feedback, many registered dietitians who are Medicare providers are certified diabetes educators, so these services would be very appropriate for them to perform and report on. As such, we agreed with the feedback and propose to add to the Nutrition/Dietician specialty set.
	0416/ N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear**: Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association	We propose to include this measure in the Nutrition/ Dietician specialty set as it is clinically relevant to this clinician type. Based on previous stakeholder feedback, many registered dietitians who are Medicare providers are certified diabetes educators, so these services would be very appropriate for them to perform and report on. As such, we agreed with the feedback and propose to add to the Nutrition/Dietician specialty set.

B.25. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE NUTRITION/DIETICIAN SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance	This measure is being proposed for removal from this specialty set beginning with the 2024 MIPS payment year. Nutrition/ Dietician specialty specific coding was not finalized for inclusion for the 2022 performance period. Therefore, we propose to remove the measure from the Nutrition/Dietician specialty set as it is no longer relevant to this specialty.

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Obstetrics/Gynecology specialty set.

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	309	CMS124v 10	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
* §	N/A / N/A	310	CMS153v 10	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication.	Centers for Medicare & Medicaid Services

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
* § ! (Appropriate Use)	N/A / 3475e	472	CMS249v4	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OBSTETRICS/GYNECOLOGY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Oncology/Hematology specialty set.

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
*	0041 / 0041e	110	CMS147 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* §	0028 / 0028e	226	CMS138 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	374	CMS50v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology
§	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
§ ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
§ ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	462	CMS645 v5	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.27a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ONCOLOGY/HEMATOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	American Society of Hematology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	317	CMS22 v10	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented**: Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Radiation Oncology specialty set.

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology

B.27b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE RADIATION ONCOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Ophthalmology specialty set.

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0086 / 0086e	012	CMS143v 10	eCQM Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v1 1	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0565 / 0565e	191	CMS133v 10	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
* §	0028 / 0028e	226	CMS138v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.28. Ophthalmology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE OPHTHALMOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0087 / N/A	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	019	CMS142v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communicati on and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.29. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Orthopedic Surgery specialty set.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v10	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68 v11	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	134	CMS2v 11	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years− with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years− with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years− with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS13 8v10	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
* ! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	375	CMS66 v10	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	N/A / N/A	376	CMS56 v10	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years ı with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.29. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET

Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUII), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.30. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Otolaryngology specialty set.

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine

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PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications. CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Otolaryngology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.31. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pathology specialty set.

B.31. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
§	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.32. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Pediatrics specialty set.

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS 154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS 146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS 147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	N/A / N/A	134	CMS 2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
* §	N/A / N/A	239	CMS 155v10	eCQM Specifications	Process	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	N/A / N/A	240	CMS 117v10	eCQM Specifications	Process	Community/ Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS 137v10	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. • Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	310	CMS 153v10	eCQM Specifications	Process	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	366	CMS 136v11	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* § ! (Outcome)	0710 / 0710e	370	CMS 159v10	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	N/A / N/A	379	CMS 74v11	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / 1365e	382	CMS 177v10	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica

B.32. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication /Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUII):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
§	N/A / N/A	394	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pediatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PEDIATRICS SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.33. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Medicine specialty set.

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.33. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101/ N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	317	CMS22 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.34. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Physical Therapy/Occupational Therapy specialty set.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient= Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v10	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology
! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS139v10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.34. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	050	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
0101/ N/A	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.35. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Plastic Surgery specialty set.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.35. Plastic Surgery

MEASURES PROPOSED FOR **ADDITION** TO THE PLASTIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A/ N/A	128	CMS69v10	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services	We propose to include this measure in the Plastic Surgery specialty set as it is clinically relevant to this clinician type. Stakeholders commented, and we agreed, that this is a measure consistently reported by their MIPS eligible clinicians. BMI does impact plastic surgery outcomes, therefore, is clinically relevant to the Plastic Surgery specialty set.

B.35. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PLASTIC SURGERY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented**: Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.36. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Podiatry specialty set.

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0101 / N/A	318	CMS139v 10	eCQM Specifications, CMS Web Interface Measure Specifications	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.36. Podiatry

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PODIATRY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.37. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Preventive Medicine specialty set.

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347v5	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v4	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.37. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented**: Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.38. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable. We request comment on the measures available in the proposed Pulmonology specialty set.

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
*	0041 / 0041e	110	CMS147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.38. Pulmonology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PULMONOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma**: The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.39. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Rheumatology specialty set.

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	0326 / N/A	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS127 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
*	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v10	Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE RHEUMATOLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Hiigh Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.40. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Skilled Nursing Facility specialty set.

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS 145v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS 144v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS 147v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
*	N/A / N/A	111	CMS 127v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS 156v10	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.40. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE SKILLED NURSING FACILITY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0101/ N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.41. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Speech Language Pathology specialty set.

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	N/A / N/A	134	CMS2v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* § ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.41. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.42. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Thoracic Surgery specialty set.

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS 68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS 138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user .	National Committee for Quality Assurance
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS 50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.42. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE THORACIC SURGERY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	044	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.43. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urgent Care specialty set.

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.43. Urgent Care

PREVIOUSLY FINALIZED MEASURES PRPOSED FOR **REMOVAL** FROM THE URGENT CARE SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.44. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Urology specialty set.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0389 / 0389e	102	CMS129 v11	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research
* §	0062 / N/A	119	CMS134 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Safety)	N/A / N/A	130	CMS68v 11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v 10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.44. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
*	N/A / N/A	462	CMS645 v5	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute
* ! (Outcome)	N/A / N/A	476	CMS771 v3	eCQM Specifications	Patient-Reported Outcome-Based Performance Measure	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUS) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.44. Urology

MEASURES PROPOSED FOR **ADDITION** TO THE UROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Appropriate Use)	N/A/ N/A	TBD	CMS646 v2	eCQM Specifications	Process	Effective Clinical Care	**Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer**: Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of initial diagnosis	Oregon Urology	We propose to include this measure in the Urology specialty set as it is clinically relevant to this clinician type. Given the high rates that patients are assessed, treated, and managed for this condition within this specialty, we recommend the inclusion of this measure within the Urology specialty set. See Table A.1 for rationale.

B.44. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A/ N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair**: Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

B.45. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that are proposed to be added, and measures that are proposed for removal, as applicable. We request comment on the measures available in the proposed Vascular Surgery specialty set.

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
§ ! (Patient Safety)	N/A / N/A	130	CMS68v11	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
* ! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v10	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient-Reported Outcome-Based Performance Measure	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND • Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality

B.45. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE VASCULAR SURGERY SET Note: In this this proposed rule, we propose the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0268/ N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A/ N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight IIeparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.
N/A / N/A	317	CMS22v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services	This measure is being proposed for removal beginning with the 2024 MIPS payment year. See Table C for rationale.

TABLE Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 19 previously finalized quality measures from the MIPS Program for the 2022 MIPS performance period/2024 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 PFS final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), additional criteria that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent. Beginning with the 2020 MIPS performance period/2022 MIPS payment year, we also refer readers to the CY 2020 PFS final rule (84 FR 62957 through 62959) for additional quality measure removal criteria.

TABLE Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

C.1. Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
NQF # / eCQM NQF #:	0087 / NA
Quality #:	014
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12 month performance period.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle. Given this measure's continued topped out status (82 FR 53640), we believe it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.2. Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	019
CMS eCQM ID:	CMS142v10
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Measure Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative. This is a process measure that is a standard of care requiring only the that results were communicated, which by itself may not have a meaningful direct impact on patient care as no follow-up or confirmation of care coordination is required. Additionally, the MIPS CQMs Specifications collection type is in the third year of the topped out lifecycle (82 FR 53640).
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.3. Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin

Category	Description
NQF # / eCQM NQF #:	0268 / N/A
Quality #:	021
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.
Measure Steward:	American Society of Plastic Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure steward will not be further reviewing or updating the measure specifications. In addition, this measure has reached the end of the topped out lifecycle (82 FR 53640). Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and the measure has become standard of care. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.4. Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	023
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.
Measure Steward:	American Society of Plastic Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure steward will not be further reviewing or updating the measure specifications. In addition, this measure has reached the end of the topped out lifecycle (82 FR 53640). Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and the measure has become standard of care. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.5. Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	044
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle (82 FR 53640) and has a high performance rate of 96.08 percent for the MIPS CQMs Specifications collection type. Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes and should be a standard of care. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.6. Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	050
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it splits a clinical process into individual quality measures. In order to align with the Meaningful Measures Initiative, we plan to maintain measure Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older. We recognize measure Q048 does not quantify the completion of plan of care but includes the assessment for the presence or absence of urinary incontinence within a broader patient population. Measure Q050 is limited to patients that were screened positive for urinary incontinence which results in an incomplete patient population being evaluated; whether screened for urinary incontinence or being voluntarily verbalized by the patient. We believe as a stand-alone measure it is not a true reflection of the quality of care being given, but only reflects care to a subpopulation of patients with documented urinary incontinence. To truly ensure quality of care for these patients, we believe that clinicians should engage patients and perform this assessment for all denominator eligible patients at risk for the presence or absence of urinary incontinence. Additionally, the Medicare Part B Claims Specifications collection type is at the end of the topped out lifecycle (82 FR 53640).
In the Circumstance the Measure is Retained	We would update the denominator eligible encounters to add coding for Physical Therapy MIPS eligible clinician type and add the measure to the Physical Therapy/Occupational Therapy specialty measure set.

C.7. Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	067
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.8. Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	070
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.9. Melanoma: Continuity of Care – Recall System

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	137
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as the measure is not advancing quality care but offers performance by simply establishing a recall system. Despite this structure supporting patient care, it does not measure quality care that directly impacts patients. We believe this measure is not providing a meaningful impact to quality improvement.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.10. Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
NQF # / eCQM NQF #:	0383 / N/A
Quality #:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Measure Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it splits a clinical process into individual quality measures. In order to align with the Meaningful Measures Initiative, we plan to maintain measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. We recognize measure Q144 does not quantify the completion of a plan of care but includes the assessment of pain for patients undergoing cancer treatment. Measure Q144 is limited to those patients that were screened positive for pain; whether screened for pain or being voluntarily verbalized by the patient. We believe as a stand-alone measure it is not a true reflection of the quality of care being given, but only reflects care to a subpopulation of oncology patients with documented pain. To truly ensure quality of care for these patients, we believe that clinicians should engage all denominator eligible patients and perform this assessment to identify the presence of pain in patients undergoing cancer treatment.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.11. Falls: Risk Assessment

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality #:	154
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle (82 FR 53640). Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.12. Radiology: Stenosis Measurement in Carotid Imaging Reports

Category	Description
NQF # / eCQM NQF #:	0507 / N/A
Quality #:	195
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.
Measure Steward:	American College of Radiology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle (82 FR 53640) and has a high performance rate of 95.62 percent for the Medicare Part B Claims Specifications collection type and 97.47 percent for the MIPS CQMs Specifications collection type. Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The average performance rate and topped out status is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.13. Radiology: Reminder System for Screening Mammograms

Category	Description
NQF # / eCQM NQF #:	0509 / N/A
Quality #:	225
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it represents a structure measure rather than a measure that supports direct patient care. In addition, the performance on the MIPS CQMs Specifications collection type is extremely high and unvarying, making this measure extremely topped out for this collection type as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this measure is 98.37 percent for the MIPS CQMs Specifications collection type. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1275/2021%20MIPS%20Quality%20Benchmarks.zip.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.14. Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	317
CMS eCQM ID:	CMS22v10
National Quality Strategy Domain:	Community/Population Health
Collection Type:	Medicare Part B Claims Specifications, eCQM Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.
Measure Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it is low-bar and a frequently performed assessment. This is a process measure that only requires a blood pressure to be taken and if abnormal a follow-up plan of care be documented; however, the documented follow-up includes referring the patient to a primary care physician and does require confirmation of follow-up. Additionally, the measure does not strive to ensure adequate control of blood pressure as patients with an active diagnosis of hypertension are excluded from the denominator eligible patient population. While screening patients for high blood pressure is an important piece of quality care, it is the controlling of high blood pressure which reduces patient clinical risks and truly drives positive patient outcomes. This quality action is already available in measure Q236: Controlling High Blood Pressure.
In the Circumstance the Measure is Retained	We would update the description to replace 'pre-hypertensive' with 'elevated'. Additionally, the definition for all collection types would be revised to reflect 2017 ACC/AHA guidelines; including, changing blood pressure classifications, relevant thresholds, and applicable interventions. The eCQM Measure Specifications collection type would be revised to have the logic apply to exceptions based on blood pressure classification to more accurately capture a patient declining applicable intervention(s). This measure would also be removed from the Thoracic Surgery specialty measure set.

C.15. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative to measure Q176: Tuberculosis Screening Prior to First Course Biologic Therapy because we are proposing in Table D.20 substantive changes to measure Q176 that would broaden the denominator by including an expanded list of biologic therapies that capture much of the denominator patient population for this measure.
In the Circumstance the Measure is Retained	We would update the denominator to include only those patients who are on a biologic immune response modifier prescribed within the current measurement period. There is no specialty set movement proposed for this measure.

C.16. Pain Brought Under Control Within 48 Hours

Category	Description
NQF # / eCQM NQF #:	0209 / N/A
Quality #:	342
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.
Measure Steward:	National Hospice and Palliative Care Organization
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it does not align with the Meaningful Measures Initiative. This measure should be a standard of care given it represents a central pillar of quality palliative care by supporting effective pain management for patients. As currently specified, this measure only assesses if pain was brought to a comfortable level within 48 hours of the initial assessment and does not ensure treatment is aligned with patient goals, a plan of care for the duration of palliative care, and current guidelines; additionally, it may not be feasible dependent upon the medication and delivery method (i.e., procedural versus oral medication administration). It is important to incorporate shared-decision making and patient engagement while in palliative care, which may not always align with the time constraint of the measure.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.17. Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	429
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it does not show meaningful measurement. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.18. Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	434
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.
Measure Steward:	American Urogynecologic Society
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the Meaningful Measures Initiative as it is duplicative in denominator patient population to measure Q432: Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair with the quality action being completed concurrently. Additionally, the limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.19. Medication Management for People with Asthma

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	444
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the CY 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

NOTE: Electronic clinical quality measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

The D Tables within the NPRM provide the substantive changes proposed for the quality measures in CY 2022. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2022 may not be identified within the NPRM due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2022 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2023. The 2022 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but we believe are important to communicate to stakeholders. These changes align with the scope of the current coding; however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2022 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes. Language has also been added, to all applicable 2022 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the D table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

It should be noted that in the 2021 PFS final rule (85 FR 84870), the CMS Web Interface Measures Specifications collection type would sunset starting with the CY 2022 MIPS performance period; however, in section IV.A.3.d.(1)(d) of this proposed rule, we are proposing to extend the availability of the CMS Web Interface measures as a collection type for the 2022 MIPS performance period and sunset the CMS Web Interface measures starting with the CY 2023 MIPS performance period. Therefore, we are proposing substantive changes to the CMS Web Interface Measure Specifications collection type as outlined in the applicable measures within the D tables. In conjunction with seeking public comment on the proposal to extend the availability of the CMS Web Interface measures as a collection type, we are seeking public comment on the substantive changes proposed for the CMS Web Interface Measure Specifications collection type given that the CMS Web Interface Measure Specifications collection type has generally remained the same for three consecutive (CY 2019, CY 2020, and CY 2021) MIPS performance periods.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. 3. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Revised:** Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator confirmation: For the CMS Web Interface Measure Specifications collection type: Revised:** Determine if the patient has an active diagnosis of diabetes during the measurement period OR an active diagnosis of diabetes during the year prior. - If the patient has an active diagnosis of diabetes in the medical record, select "Yes" **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used. **Updated guidance: For the CMS Web Interface Measure Specifications colleciton type: Added:** Do not include HbA1c levels reported by the patient. **Updated numerator guidance: For the CMS Web Interface Measure Specifications colleciton type: Removed:** - Patient Reported Requirement: Date and most recent value (distinct value required) **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** 1. Palliative care services provided to patient any time during the measurement period
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose that the denominator exclusion language be updated for all collection types, except for the CMS Web Interface Measure Specifications collection type, to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We propose to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component. We propose to update the denominator exclusion language for the CMS Web Interface Measure Specifications collection type, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, the denominator confirmation was updated to clarify that the diagnosis should be active during the performance period or year prior. We propose to update the guidance for the CMS Web Interface Measure Specifications collection type to ensure that patient reported IIbA1c levels should not be utilized for quality action assessment for the purposes of this measure.

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated definition: For the eCQM Specifications collection type: Added:** The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients. **Updated value set/coding: For the eCQM Specifications collection type: Revised:** "Pregnancy" (2.16.840.1.113883.3.526.3.378) value set to more accurately capture pregnancy state
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type definition section to align the measure language with the logic to allow for quantitative or qualitative documentation of moderate or severe left ventricular systolic dysfunction (LVSD). Additionally, we propose to update the eCQM Specifications "Pregnancy" value set to more accurately capture the state of pregnancy to ensure the denominator exclusion is being applied to the correct patient population.

D.3 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated definition: For the eCQM Specifications collection type: Added:** LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction (LVSD). The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients. **Updated denominator logic: For the eCQM Specifications collection type: Revised:** Myocardial Infarction timing logic to use the start date for the myocardial infarction. **Updated value set/coding: For the eCQM Specifications collection type: Revised:** "Coronary Artery Disease No MI" (2.16.840.1.113883.3.526.3.369) to remove coding related to Dressler's Syndrome. **Updated denominator note: For the MIPS CQM Specifications collection type: Added:** Submission Criteria 1: LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction (LVSD). The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type definition section to align the measure language with the logic to allow for quantitative or qualitative documentation of moderate or severe left ventricular systolic dysfunction (LVSD). We propose to update the denominator logic for the eCQM Specifications collection type to use the start date for the myocardial infarction. This will ensure those patients without a documented myocardial infarction end date within the medical record will be captured within the measure denominator as these patients would be appropriate for the denominator eligible patient population. Additionally, we propose to remove 'Dressler's Syndrome' from the "Coronary Artery Disease No MI" value set for the eCQM Specifications collection type as this is not a conclusive diagnosis to indicate coronary artery disease and therefore, not appropriate for this value set.

D.4 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated definition: For the eCQM Specifications collection type: Added:** The LVSD may be determined by quantitative or qualitative assessment, which may be current or historical. Examples of a quantitative or qualitative assessment may include an echocardiogram: 1) that provides a numerical value of LVSD or 2) that uses descriptive terms such as moderately or severely depressed left ventricular systolic function. Any current or prior ejection fraction study documenting LVSD can be used to identify patients
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type definition section to align the measure language with the current measure logic to allow for quantitative or qualitative documentation of moderate or severe left ventricular systolic dysfunction (LVSD).

D.5 Anti-Depressant Medication Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	009
CMS eCQM ID:	CMS128v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).
Substantive Change:	**Updated denominator exclusion: Revised:** Exclude patients who are in hospice care for any part of the measurement period
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion to remove the term 'overlaps' and replace with plain language for clarity and to ensure consistency in implementation.

D.6 Appropriate Treatment for Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v10
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude URI episodes when the patient had hospice care for any part of the measurement period. 2. Exclude URI episodes when the patient had an active prescription of antibiotics in the 30 days prior to the episode date, including the episode date up until the time of the encounter. **Updated logic and logic definitions: For the eCQM Specifications collection type: Revised:** logic so definitions point to the encounter as a basis for evaluating other clinical data. **Updated value set/coding: For the eCQM Specifications collection type: Added:** value sets "Observation care discharge day management", "Home Healthcare Services", "Medical Disability Exam", and "Observation". **Updated denominator: For the MIPS CQMs Specifications collection type:** Added: Home Health setting and coding for Work Related or Medical Disability Evaluation services. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Revised:** URI episodes when the patient had an active prescription of antibiotics (Table 1) in the 30 days prior to the episode date.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type denominator exclusion to remove the term 'overlapping' and replace with plain language for clarity and to ensure consistency in implementation. Additionally, we propose to revise the denominator exclusion to align with the logic regarding the timing of the active prescription and the encounter for the purposes of this exclusion. We propose to update the eCQM Specifications collection type logic so that the definitions point to the encounter as a basis for evaluation of other clinical data as this will align with the measure intent and ensure appropriate time intervals for implementation. Additionally, we propose to add value sets to the eCQM Specifications collection type as these value sets are appropriate and applicable to this measure's denominator eligibility. We propose to revise the MIPS CQMs Specifications collection type denominator exclusion to clarify that all patients with active antibiotic prescriptions up to the time of the encounter should be excluded from the denominator eligible patient population. Additionally, we propose to update the denominator eligible coding to include home visits and disability evaluation services as these are appropriate and applicable clinical settings. In the event the proposed substantive change(s) are finalized, for the MIPS CQMs Specifications collection type, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.7 Appropriate Testing for Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v10
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** 1. Exclude episodes where the patient is taking antibiotics in the 30 days prior to the episode date, or had an active prescription on the episode date. 3. Exclude episodes where the patient is in hospice care for any part of the measurement period. **Updated denominator logic: For the eCQM Specifications collection type: Revised:** definitions to point to the encounter as a basis for evaluating other clinical data **The measure guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. The intent is to determine whether antibiotics are being dispensed appropriately. Antibiotics should only be dispensed if a strep test has been performed to confirm a bacterial infection. Antibiotics should not be dispensed for viral infections. This eCQM is an episode-based measure. An episode is defined as each eligible encounter for patients aged 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event during the measurement period. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure initial patient population/denominator is revised to read: For all collection types:** Outpatient, telephone, online assessment (i.e. e-visit or virtual check-in), observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispensing event on or within 3 days after the episode date among patients 3 years or older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Revised:** Prescribed or dispensed antibiotic on or within 3 days after the episode date (Table 1). **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Revised:** Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date, or had an active prescription on the episode date.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type denominator exclusions to clarify timing of exclusion criteria and to remove the term 'overlap' and replace with plain language for clarity and to ensure consistency in implementation. We propose to update the eCQM Specifications collection type logic so that the definitions point to the encounter as a basis for evaluation of other clinical data as this will align with the measure intent and ensure appropriate time intervals for implementation. We propose to update the eCQM Specifications collection type guidance section to clarify the intent of the measure and appropriate antibiotic dispensing. Additionally, we propose to update the eCQM Specifications collection type initial patient population to capture those patients with an antibiotic dispensing event on or within 3 days after the episode event to align with intent of the measure. We propose to update the denominator and denominator criteria of the MIPS CQMs Specifications collection type to reflect that patients with an antibiotic dispensing event on or within 3 days after the episode event should be included within the denominator eligible population as this aligns with the intent of the measure to assess appropriate antibiotic dispensing. We propose to revise the MIPS CQMs Specifications collection type denominator exclusion to clarify that all patients with active antibiotic prescriptions up to the time of the encounter should be excluded from the denominator eligible patient population.

D.8 Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	0654 / N/A
Quality#:	093
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.

D.9 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Category	Description
NQF # / eCQM NQF #:	0389 / 0389e
Quality#:	102
CMS eCQM ID:	CMS129v11
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**Updated denominator criteria: For the MIPS CQMs Specifications collection type: Revised:** Any patient, regardless of age **The measure instructions are revised to read: For the MIPS CQMs Specifications collection type:** This measure is to be submitted once per performance period for patients with a diagnosis of prostate cancer at low (or very low) risk of recurrence who receive interstitial prostate brachytherapy, external beam radiotherapy to the prostate, radical prostatectomy during the performance period. The quality-data code or equivalent needs to be submitted only once during the performance period. It is anticipated that Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the listed procedures as specified in the denominator coding will submit this measure. **Updated denominator note: For the MIPS CQMs Specification collection type: Added:** Most recent risk assessment of recurrence completed before the first prostate cancer treatment during the performance period will be used for denominator eligibility.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the MIPS CQMs Specifications collection type to remove the gender specificity from the denominator criteria to ensure a complete patient population. Additionally, we propose to revise the measure instructions and denominator note for the MIPS CQMs Specifications collection type to reflect the update in measure submission frequency from once per episode to once per performance period utilizing the most recent risk assessment for purposes of denominator eligibility, as this is more aligned with the measure intent as well as bringing all collection types into alignment.

D.10 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality#:	110
CMS eCQM ID:	CMS147v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Updated guidance: For the eCQM Specifications collection type: Added:** Patient self-report for procedures as well as immunizations should be recorded in 'Procedure, Performed' template or 'Immunization, Administered' template in QRDA-1. **Updated value set/coding: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types: Removed:** "Previous Receipt of Influenza Vaccine" (2.16.840.1.113883.3.526.3.1185) value set.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type in order to accurately capture those patients who had previously received the influenza immunization. The current logic definition does not capture the date of immunization receipt nor does it ensure the patient was assessed during the flu season and is not fully aligned with measure intent. Therefore, the value set "Previous Receipt of Influenza Vaccine" will be removed from the measure and the guidance section will be updated to outline the process for capturing those patients who have previously received the influenza immunization for the purposes of this measure. Additionally, the value set "Previous Receipt of Influenza Vaccine" will be removed from CMS Web Interface Measure Specifications collection type to align with the eCQM Specifications collection type, however, this will not impact the numerator of the measure. Medical record documentation of previous receipt of the influenza vaccine during the flu season will still suffice for completion of the quality action, though this value set will no longer be available for mapping purposes.

D.11 Pneumococcal Vaccination Status for Older Adults

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	111
CMS eCQM ID:	CMS127v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.
Substantive Change:	**The measure description is revised from 'Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine' to:** Percentage of patients 66 years of age and older who have ever received a pneumococcal vaccine. **The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** Exclude patients who are in hospice care for any part of the measurement period. **Updated initial patient population: For the eCQM Specifications collection type: Revised:** patient age changed to 66 years of age or older. **The measure numerator is revised to read: For all collection types:** Patients who received a pneumococcal vaccination on or after their 60th birthday and before the end of the measurement period; or had an adverse reaction to the vaccine before the end of the measurement period. **Updated value set/coding: For the eCQM Specifications collection type: Revised:** **Removed:** "Pneumococcal Vaccine" (2.16.840.1.113883.3.464.1003.110.12.1027) and "Pneumococcal Vaccine Administered" (2.16.840.1.113883.3.464.1003.110.12.1034) **Added:** "Pneumococcal Polysaccharide 23 Vaccine" (2.16.840.1.113883.3.464.1003.110.12.1089) **The measure denominator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients 66 years of age and older with a visit during the measurement period **The measure denominator criteria is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients aged > 66 years on date of encounter **The measure denominator note is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** This measure assesses whether patients 66 years of age or older have received one or more pneumococcal vaccinations. **The measure numerator options are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Performance Met:** Pneumococcal vaccine administered on or after patient's 60th birthday and before the end of the measurement period **Performance Met:** Documentation of medical reason(s) for not administering pneumococcal vaccine (e.g., adverse reaction to vaccine) **Performance Not Met:** Pneumococcal vaccine was not administered on or after patient's 60th birthday and before the end of the measurement period, reason not otherwise specified **The measure numerator note is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** The measure provides credit for adults 66 years of age and older who have received the PPSV23 vaccine on or after the patient's 60th birthday. Patient reported vaccine receipt, when recorded in the medical record, is acceptable for meeting the numerator.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description, initial patient population, denominator, denominator criteria, and denominator note (as applicable) for all collection types to assess patients aged 66 years and older as this allows time for clinicians to administer the pneumococcal vaccination in accordance with current Advisory Committee on Immunization Practices (ACIP) recommendations. Additionally, the numerator for all collection types is proposed to be revised to assess for the administration of the pneumococcal vaccine on or after the patients 60th birthday and before the end of the measurement period or documentation of medical reason(s) for not administering the pneumococcal vaccine. We propose to update the eCQM Specifications collection type denominator exclusion to remove the term 'overlaps' and replace with plain language for clarity and to ensure consistency in implementation. Additionally, we propose to update the value sets for the eCQM Specifications collection type to reflect the updates to the measure to align with current ACIP recommendations that all adults age 65 years and older receive one dose of the 23-valent pneumococcal polysaccharide vaccine (PPSV23). The MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection type will also be updated to only allow for the PPSV23 vaccine to suffice for numerator compliance. We propose to update the numerator options for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for the receipt of the pneumococcal vaccine on or after the patient's 60th birthday or the documentation of medical reasons, such as an adverse reaction, to meet the quality action of this measure as it better aligns with current ACIP recommendations. Additionally, we propose to update the MIPS CQMs Specifications and the Medicare Part B

Category	Description
	Claims Measure Specifications collection types by revising the Numerator Note in order to align with current ACIP recommendations and clarify that patient self-reporting is allowable for this measure's required clinical quality action.

D.12 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** 1. Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Palliative care services used by patient any time during the measurement period **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Patient reported mammograms, when recorded in the medical record, are acceptable for meeting the numerator. **For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We propose to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component. Additionally, we propose to add a numerator note to the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for patient self-report as this is appropriate to avoid overtreatment. We propose to update the denominator exclusion language for the CMS Web Interface Measure Specifications collection type, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period.

D.13 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** 1. Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** 1. Patient was provided palliative care services any time during the measurement period **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Patient reported procedures and diagnostic studies, when recorded in the medical record, are acceptable for meeting the numerator. **For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We propose to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component. Additionally, we propose to add a numerator note to the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for patient self-report as this is appropriate to avoid overtreatment. We propose to update the denominator exclusion language for the CMS Web Interface Measure Specifications collection type, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period.

D.14 Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.
Substantive Change:	**Updated denominator exclusion: Revised:** Acute bronchitis/bronchiolitis episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to the episode date. **Updated numerator instructions: Removed:** Ticarcillin clavulanate and Erythromycin sulfisoxazole from Table 1 - Antibiotic Medications
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion to clarify that all patients with active antibiotic prescriptions up to the time of the encounter should be excluded from the denominator eligible patient population. We propose to update Table 1 – Antibiotic Medications to ensure the list includes current and appropriate medications for the purposes of this measure. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.15 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **The measure guidance is revised to read: For the eCQM Specifications collection type:** Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included. The eye exam must be performed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** 1. Palliative care services provided to patient any time during the measurement period **The measure numerator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Patients with an eye screening for diabetic retinal disease. This includes diabetics who had one of the following: • Diabetic with a diagnosis of retinopathy during the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period • Diabetic with no diagnosis of retinopathy during the measurement period and a retinal or dilated eye exam by an eye care professional in the measurement period or the year prior to the measurement period **The measure numerator note is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** The eye exam must be performed or reviewed by an ophthalmologist or optometrist, or there must be evidence that fundus photography results were read by a system that provides an artificial intelligence (AI) interpretation. Alternatively, results may be read by a qualified reading center that operates under the direction of a medical director who is a retinal specialist **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the description of the measure to remove the term 'overlaps' and replace with plain language for clarity and to ensure consistency in implementation. Additionally, we propose to update the numerator for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to remove the terms 'overlaps' and 'overlapping' and replace with plain language for clarity and to ensure consistency in implementation. We propose that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured.

Category	Description
	Additionally, we propose to update the guidance for the eCQM Specifications collection type and numerator note for the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types to allow for the use of artificial intelligence as it is applicable and clinically appropriate for numerator compliance for this measure. We propose to revise the denominator note for the MIPS CQMs Specifications collection type and the numerator note for the Medicare Part B Claims Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component.

D.16 Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality#:	119
CMS eCQM ID:	CMS134v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients receiving palliative care during the measurement period. **Updated value set/coding: For the eCQM Specifications collection type: Removed:** coding related to transplant donors from "Kidney Transplant" (2.16.840.1.113883.3.464.1003.109.12.1012) value set. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For the MIPS CQMs Specifications collection types:** **Added:** 1. Patients who use palliative care services any time during the measurement period
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. Additionally, we propose to update the "Kidney Transplant" value set to remove coding related to kidney transplant donors as it would be appropriate for these patients to still receive a screening for nephropathy. We propose to revise the denominator note for the MIPS CQMs Specifications collection type to clarify the timing for those exclusions that have an age-related component.

D.17 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.
Substantive Change:	**The measure denominator exclusion is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** 1. Documentation stating the patient has received or is currently receiving palliative or hospice care 2. Documentation of patient pregnancy anytime during the measurement period prior to and including the current encounter
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator exclusions to increase clarity and add specificity to ensure the appropriate patient population is being excluded from the assessment of the quality action.

D.18 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v11
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**The measure description is revised to read: For the CMS Web Interface Measure Specifications collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **The measure guidance is revised to read: For the eCQM Specifications collection type:** The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the diagnosis or treatment of depression. This measure does not require documentation of a specific score, just whether results of the normalized and validated depression screening tool used are considered positive or negative. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. This eCQM is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. * The depression screening must be reviewed and addressed by the provider filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. In order to satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression: * A clinician should only order pharmacological intervention when appropriate and after sufficient diagnostic evaluation. However, for the purposes of this measure, additional screening and assessment during the qualifying encounter will not qualify as a follow-up plan. * A clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **For the CMS Web Interface Measure Specifications collection type:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. This is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. This measure does not require documentation of a specific score, just whether results of the normalized and validated depression screening tool used are considered positive or negative. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record * The depression screening must be reviewed and addressed by the provider, filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention

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	as determined by the provider practice * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a provider practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression, a clinician should: *Only order pharmacological intervention when appropriate and after sufficient diagnostic evaluation. However for the purposes of this measure, additional screening and assessment during the qualifying encounter will not qualify as a follow-up plan. *Opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. **Updated guidance denominator: For the CMS Web Interface Measure Specifications collection type: Revised:** The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Revised:** Patients who have been diagnosed with depression or with bipolar disorder. **The measure numerator instructions are revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Numerator Instructions: A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a provider for additional evaluation, pharmacological interventions, or other interventions for the treatment of depression. This is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. This measure does not require documentation of a specific score, just whether results of the normalized and validated depression screening tool used are considered positive or negative. Each standardized screening tool provides guidance on whether a particular score is considered positive for depression. The depression screening must be reviewed and addressed by the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. In order to satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Should a patient screen positive for depression, a clinician should: • Only order pharmacological intervention when appropriate and after sufficient diagnostic evaluation. However, for the purposes of this measure, additional screening and assessment during the qualifying encounter will not qualify as a follow-up plan. • Opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan **Updated definitions (numerator): For the CMS Web Interface Measure Specifications collection type: Revised:** Follow-Up Plan: Documented follow-up for a positive depression screening must include one or more of the following: • Referral to a provider for additional evaluation and assessment to formulate a follow-up plan for a positive depression screen • Pharmacological interventions • Other interventions or follow-up for the diagnosis or treatment of depression **Updated numerator submission guidance: For the CMS Web Interface Measure Specifications collection type: Removed:** If recommended follow-up is additional evaluation or assessment, the additional evaluation or assessment must occur at the eligible encounter. **Revised:** Submission Guidance: Numerator Submission, Guidance Note: Use most recent screening for depression which occurred either during the encounter or up to 14 days prior to the encounter

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	Although the patient may have access to the depression screening tool in advance of the encounter, the depression screening results must be documented on the date of the encounter. The results must be reviewed/verified and documented by the eligible professional in the medical record on the date of the encounter to meet the screening portion of this measure. **Updated numerator option: For the CMS Web Interface Measure Specifications collection type: Revised:** Medical Reason(s) Documentation of medical reason for not screening patient for depression (e.g., cognitive, functional, or motivational limitations that may impact accuracy of results; patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status)
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications and CMS Web Interface Measure Specifications collection types guidance section to remove the requirement for an in-office review of the assessment as it is appropriate to allow this to be completed via telehealth encounter, clarify requirements as only documentation of a negative or positive depression screening is needed to align with the intent of the measure, and revise the numerator compliant follow-up plans based on stakeholder feedback to ensure clinical appropriateness. We propose to update the CMS Web Interface Measure Specification collection type description, guidance sections, definitions, and numerator sections to provide clarity as to what constitutes a follow-up plan. Additionally, language throughout the measure specification was updated allowing for alignment with clinical workflow. The measure assesses the most recent depression screening completed either during the encounter or up to 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening to count towards a follow-up, since that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Additionally, suicide risk assessments have been removed as a numerator compliant follow-up plan option as this should be completed when appropriate and based on the assessment by the clinician regarding the severity of the patient's symptoms of depression at the time of depression screening. We also propose to update the measure language and denominator exclusions to reflect that this measure is screening of depression for patients who have not been previously diagnosed or have an active diagnosis of depression or bipolar disorder. This preventive measure assesses screening and follow up plan for patients that are screened positive for depression. The denominator exception was revised in order to streamline the language. We propose to update the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types numerator instructions to clarify requirements as only documentation of a negative or positive depression screening is needed to align with the intent of the measure and revise instructions for the numerator compliant follow-up plans based on stakeholder feedback to ensure clinical appropriateness.

D.19 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v10
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**The measure guidance is revised to read: For the eCQM Specifications collection type:** This eCQM is an episode-based measure. An episode is defined as each eligible encounter for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face or telehealth interaction. Due to the nature of some applicable coding related to radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face or telehealth encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face or telehealth encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy on the same day as the encounter or during the 30 days before the date of the encounter AND during the 30 days after the date of the encounter. Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, visual analog scale, a categorical scale, or pictorial scale. Examples include the Faces Pain Rating Scale and the Brief Pain Inventory (BPI). This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM **Updated value set/coding: For the eCQM Specifications collection type: Removed:** Topical chemotherapy from value set "Chemotherapy Administration" (2.16.840.1.113883.3.526.3.1027) and coding for neurofibromatosis from value set "Cancer" (2.16.840.1.113883.3.526.3.1010). **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** **Removed:** Submission critiera one coding related to neurofibromatosis. **Revised:** Patient procedure on or within 30 days before denominator eligible encounter AND Patient procedure on or within 30 days after denominator eligible encounter **Updated instructions: For the MIPS CQMs Specifications collection type: Revised:** NOTE: For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter, where the patient and physician have a face-to-face or telehealth interaction. Due to the nature of some applicable coding related to the radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face or telehealth encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face or telehealth encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy on the same day as the encounter or during the 30 days before the date of the encounter AND during the 30 days after the date of the encounter
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the eCQM Specifications guidance section to align the statement regarding timing of chemotherapy to ensure alignment with the logic timing constraints and added language for telehealth encounters as they are appropriate for inclusion for assessment of quality action completion. Additionally, we propose to remove topical chemotherapy from the "Chemotherapy Administration" value set and neurofibromatosis from the "Cancer" (2.16.840.1.113883.3.526.3.1010) value set as these patient populations are not appropriate for inclusion within the initial patient population for the purposes of clinical quality action assessment. We propose to remove coding related to neurofibromatosis from the MIPS CQMs Specifications collection type denominator criteria for Submission Criteria One as this patient population is not appropriate for inclusion with the denominator eligible patient population for the purposes of clinical quality action assessment. Additionally, the denominator criteria was revised to clarify the timing of the chemotherapy and align with the intent of the measure. We propose to update the MIPS CQMs Specifications collection type instructions note to add clarity in timing of chemotherapy and ensure alignment throughout the measure specification in accordance with measure intent.

D.20 Tuberculosis Screening Prior to First Course Biologic Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**Updated denominator instructions:** **Revised:** Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and also have not been prescribed DMARD biologic therapy in the 15 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes **Added:** Guselkumab (Tremfya), Infliximab-axxq (Avsola), Ixekizumab (Taltz), Upadacitinib (RINVOQ) **Added:** To be included in the denominator, patient must have an encounter and a prescription for DMARD biologic therapy in the measurement period (1/1/2022-12/31/2022) WITHOUT a prior prescription for DMARD biologic therapy within the 15 months prior to the DMARD prescribed during the measurement period. **Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator instructions to include a 15-month lookback period in response to stakeholder feedback to align with clinical workflow for more established patients and to add clarity regarding the denominator eligible patient population. Additionally, the medications list was updated to align with current DMARD medications available to treat rheumatic disease. We propose to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians. This revision is not a reflection of any policy update and was made to allow those clinicians who bill exclusively through a FQHC to track their performance on the measure. This payment method is still not eligible for payment adjustments under MIPS.

D.21 Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity

Category	Description
NQF # / eCQM NQF #:	2523 / N/A
Quality#:	177
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians.

D.22 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	178
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians.

D.23 Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**Updated denominator criteria: Added:** coding for federally qualified health center (FQHC) visit.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add coding to the denominator eligibility criteria for visits that occur at a FQHC to allow of quality action assessment for these clinicians.

D.24 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **Updated numerator definition: Added:** EAT-10: A Swallowing Screening Tool, Health Partners Hearing Assessment and Tinneti Performance Oriented Mobility Assessment (POMA) as eligible standardized tools. **Revised:** Standardized Tool definition note to include speech and language capacity. Functional Outcome Deficiencies – Impairment or loss of function related to musculoskeletal/neuromusculoskeletal capacity, including but are not limited to: restricted flexion, extension and rotation, back pain, neck pain, pain in the joints of the arms or legs, and headaches OR Impairment or loss of function related to speech and language capacity, including but not limited to: swallowing, hearing, and balance disorders
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. We propose to update the numerator definition to include concepts of swallowing, hearing, and balance to the measure as it is appropriate to assess this patient population for impairment or loss of function and create a follow-up plan of care based upon any identified loss of function or impairment. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.

D.25 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type: Added:** coding for homonymous bilateral field defects and generalized contraction of visual field to the "Visual Field Defects" (2.16.840.1.113883.3.526.3.1446) value set and coding for disorders of visual cortex in (due to) inflammatory disorders to the "Disorders of Visual Cortex" (2.16.840.1.113883.3.526.3.1458) value set. **Updated denominator exclusion: For all collection types:** **Removed:** episcleritis. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type:** **Added:** diagnoses codes to the Significant Ocular Conditions 'Visual Fields Defects' for sector or arcuate defects, other localized visual field defect, homonymous and heteronymous bilateral field defects, and generalized contraction of visual field.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the eCQM Specifications collection type denominator exclusion coding to add appropriate coding for other relevant "disorders of visual field defects" and "disorders of visual cortex" diagnosis codes as these patients should not be included in the initial patient population for the assessment of the clinical quality action. The denominator exclusion coding was updated for all collection types removing diagnosis of episcleritis as a denominator exclusion as the measure steward's Technical Expert Panel (TEP) advised that this would not affect central visual acuity and as such, should not be a criteria for denominator exclusion as it would be appropriate for these patients to be assessed for best-corrected visual acuity following cataract surgery. We propose to update the denominator exclusion for the MIPS CQMs Specifications collection type to include appropriate coding for conditions to ensure the appropriate patient population is being included in the eligible denominator patient population for assessment of the clinical quality action.

D.26 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The measure description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure description to align language across Focus on Therapeutic Outcomes, Inc. (FOTO) measures in order to provide clarity to clinicians.

D.27 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The measure description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle or lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient- reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure description to align language across Focus on Therapeutic Outcomes, Inc. (FOTO) measures in order to provide clarity to clinicians.

D.28 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications | eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user
Substantive Change:	**The measure description is revised to read: For the eCQM Specifications collection type:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times during the measurement period AND who received tobacco cessation intervention if identified as a tobacco user **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. **For the CMS Web Interface Measure Specifications collection type:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months. **Updated guidance:** **For the eCQM Specifications collection type: Revised:** To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the measurement period. If a patient has multiple tobacco use screenings during the measurement period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. **For the CMS Web Interface Measure Specifications collection type: Revised:** To reflect a shortened timeframe of 12 months. **Updated value set/coding: For the eCQM Specifications and CMS Web Interface Measure Specifications collection type:** **Removed:** passive smoker from "Tobacco User" (2.16.840.1.113883.3.526.3.1170) value set. **The measure instructions are revised to read: For the MIPS CQMs Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. For implementation of the measure, the denominator eligible encounter should be used to determine if the numerator action for the tobacco cessation intervention was performed within the 12 month look back period from the date of the denominator eligible encounter. This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period 2) Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months 3) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months **For the Medicare Part B Claims Measure Specifications collection types:** This measure is to be submitted a minimum of once per performance period for patients seen during the performance period. This measure is intended to reflect the quality of services provided for preventive screening for tobacco use. For implementation of the

Category	Description
	measure, the denominator eligible encounter should be used to determine if the numerator action for the tobacco cessation intervention was performed within the 12 month look back period from the date of the denominator eligible encounter. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provided the measure-specific denominator coding. This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period 2) Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention on the date of the encounter or within the previous 12 months 3) Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months **Updated submission criteria: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Added:** The language "on the date of the encounter or within the previous 12 months" to submission criteria 2 and 3. **Updated numerator: For the eCQM Specifications collection types: Revised:** NUMERATOR (SUBMISSION CRITERIA 1): Patients who were screened for tobacco use at least once within the measurement period NUMERATOR (SUBMISSION CRITERIA 3): Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user **For the MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications, and CMS Web Interface Measure Specifications collection types: Revised:**NUMERATOR (SUBMISSION CRITERIA 1): Patients who were screened for tobacco use at least once within the measurement period NUMERATOR (SUBMISSION CRITERIA 2): Patients who received tobacco cessation intervention on the date of the encounter or within the previous 12 months NUMERATOR (SUBMISSION CRITERIA 3): Patients who were screened for tobacco use at least once within the measurement period AND who received tobacco cessation intervention if identified as a tobacco user on the date of the encounter or within the previous 12 months **Updated numerator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Replaced "12 months" with "the measurement period" for submission criteria 1 and 3. **Added:** The language "on the date of the encounter or within the previous 12 months" to submission criteria 2 and 3 in reference to tobacco cessation intervention. **Updated guidance numerator note: For the CMS Web Interface Measure Specifications collection type: Updated:** Revised language to reflect that the tobacco screening is once per performance period and tobacco cessation intervention if necessary must be completed during the encounter or previous 12 months. **Updated numerator options: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Revised:** Submission Criteria 2: **Performance Met:** Patient identified as a tobacco user received tobacco cessation intervention on the date of the encounter or within the previous 12 months (counseling and/or pharmacotherapy) **Denominator Exception:** Documentation of medical reason(s) for not providing tobacco cessation intervention on the date of the encounter or within the previous 12 months (e.g., limited life expectancy, other medical reason) **Performance Not Met:** Patient identified as tobacco user did not receive tobacco cessation intervention on the date of the encounter or within the previous 12 months (counseling and/or pharmacotherapy), reason not given Submission Criteria 3: **Denominator Exception:** Documentation of medical reason(s) for not providing tobacco cessation intervention on the date of the encounter or within the previous 12 months if identified as a tobacco user (e.g., limited life expectancy, other medical reason)
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the language for the MIPS CQMs Specifications, the Medicare Part B Measure Specifications, and CMS Web Interface Measure Specifications collection types to clarify the timing for tobacco use screening and tobacco cessation intervention for those patients identified as tobacco users. The intent of the measure is to ensure all patients are screened for tobacco use on an annual basis (each performance period) and receive tobacco cessation intervention, if identified as a tobacco user on the date of the encounter or within the previous 12 months. We propose to update the eCQM Specifications collection type to reflect that both the tobacco use screening and tobacco use intervention for those patients identified as tobacco users should occur annually (each performance period). We understand that causes a slight misalignment between the different collection types, which is due to the annual update timeline differences between the collection types. This misalignment will be reviewed in future annual update cycles. Additionally, we propose to update the eCQM Specifications and CMS Web Interface Measure Specifications collection type to "Tobacco User" value set to remove passive smoker coding as these patients are not appropriate for inclusion in the tobacco user identified patient population as they do not meet the intent of the measure and the clinical quality action would not be applicable to them. In the event the proposed substantive change(s) are finalized, for the CMS Web Interface Measure Specifications collection type, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of the substantive changes. Under MIPS, the CMS Web Interface measures are scored in comparison to quality measure benchmarks established under the Medicare Shared Savings Program. The benchmarks established for the CMS Web Interface measures are based on historical data. If a benchmark is able to be established for a CMS

Category	Description
	Web Interface measure with the proposed substantive changes, then such benchmark would be used for scoring purposes. If a benchmark is not able to be established for a CMS Web Interface measure, then the following would apply for such CMS Web Interface measure: excluded from MIPS scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the data completeness requirement is met and the applicable measure data is submitted via the CMS Web Interface.

D.29 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18 - 85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period. **Updated denominator exclusion: For the eCQM Specifications collection type:** **Revised:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients 66 and older with an indication of frailty for any part of the measurement period who meet any of the following criteria: - Advanced illness with two outpatient encounters during the measurement period or the year prior - OR advanced illness with one inpatient encounter during the measurement period or the year prior - OR taking dementia medications during the measurement period or the year prior **Added:** 1. Exclude patients 81 and older with an indication of frailty for any part of the measurement period. 2. Exclude patients receiving palliative care during the measurement period. **Revised:** Logic to allow ESRD encounter to be on or before the end of the measurement period. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** 1. Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. 2. Patients 66 – 80 years of age with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. 3. Patients 66 - 80 years of age with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. **Added:** 1. Patients 81 years of age and older with at least one claim/encounter for frailty during the measurement period. **Updated value set/coding: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types:** **Revised:** "Pregnancy" (2.16.840.1.113883.3.526.3.378) value set to more accurately capture pregnancy state. **Removed:** coding related to transplant donors from "Kidney Transplant" (2.16.840.1.113883.3.464.1003.109.12.1012) value set. **The measure guidance is revised to read: For the eCQM Specifications collection type:** In reference to the numerator element, only blood pressure readings performed by a clinician or a remote monitoring device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by a remote monitoring device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the remote monitoring device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. Do not include BP readings: -Taken during an acute inpatient stay or an ED visit -Taken on the same day as a diagnostic test or diagnostic or therapeutic procedure that requires a change in diet or change in medication on or one day before the day of the test or procedure, with the exception of fasting blood tests. -Taken by the patient using a non-digital device such as with a manual blood pressure cuff and a stethoscope. If no blood pressure is recorded during the measurement period, the patient's blood pressure is assumed "not controlled." If there are multiple blood pressure readings on the same day, use the lowest systolic and the lowest diastolic reading as the most recent blood pressure reading. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure initial patient population is revised to read: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types:** Patients 18-85 years of age who had a visit and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period.

Category	Description
	The measure denominator is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types: Patients 18-85 years of age who had a visit and diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Added:** Palliative care services given to patient any time during the measurement period **Updated denominator confirmation: For the CMS Web Interface Measure Specifications collection type: Revised:** The language to reflect the diagnosis for essential hypertenision must start before and continue into, or start during the first six months of the measurement period. **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator note: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection types:** **Revised:** The diagnosis of essential hypertension must be present some time between 1 year prior to the measurement period and the first six months of the measurement period (January 1, 2021 - June 30, 2022). **For the MIPS CQMs Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **The measure instructions note, numerator note, and narrative guidance are revised to read: For the MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications, and CMS Web Interface Measure Specifications collection types:** In reference to the numerator element, only blood pressure readings performed by a clinician or a remote monitoring device are acceptable for numerator compliance with this measure. This includes blood pressures taken in person by a clinician and blood pressures measured remotely by electronic monitoring devices capable of transmitting the blood pressure data to the clinician. Blood pressure readings taken by a remote monitoring device and conveyed by the patient to the clinician are also acceptable. It is the clinician's responsibility and discretion to confirm the remote monitoring device used to obtain the blood pressure is considered acceptable and reliable and whether the blood pressure reading is considered accurate before documenting it in the patient's medical record. Do not include BP readings: • Taken during an acute inpatient stay or an ED visit • Taken on the same day as a diagnostic test or diagnostic or therapeutic procedure that requires a change in diet or change in medication on or one day before the day of the test or procedure, with the exception of fasting blood tests. BP readings taken on the same day that the member receives a common low-intensity or preventive procedure are eligible for use. For example, the following procedures are considered common low intensity or preventive (this list is just for reference, and is not exhaustive): • Vaccinations. • Injections (e.g., allergy, vitamin B-12, insulin, steroid, toradol, Depo-Provera, testosterone, lidocaine). • TB test. • IUD insertion. • Eye exam with dilating agents. • Wart or mole removal. • Taken by the patient using a non-digital device such as with a manual blood pressure cuff and a stethoscope. If no blood pressure is recorded during the measurement period, the patient's blood pressure is assumed "not controlled." If there are multiple blood pressure readings on the same day, use the lowest systolic and the lowest diastolic reading as the most recent blood pressure reading. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** **Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the measure description to remove the term 'overlapping' and add clarity to the timing associated with the hypertension diagnosis. We propose that the denominator exclusion language be updated for all but the CMS Web Interface Measure Specifications collection type to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, for the eCQM Specifications collection type language was added to clarify timing for those exclusions that have an age-related component. For the eCQM Specifications collection type, the term 'overlaps' was removed and replace with plain language for clarity and the denominator exclusion for frailty or advanced illness was revised to update how these patients will be captured. We propose to update the CMS Web Interface Measure Specifications collection type denominator exclusions language to clarify that, for the measure, long-term care will be defined as patients staying more than 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally for the CMS Web Interface Measure Specifications collection type denominator exclusions, we propose to update the ages for the frailty and advanced illness exclusions and add an exclusion specific to those patients 81 years and older to ensure the appropriate patients are being assessed for the quality action. We propose to update the eCQM Specifications and CMS Web Interface Measure Specifications collection types "Pregnancy" value set to more accurately capture the state of pregnancy to ensure the denominator exclusion is being applied to the correct patient population and revised the logic for the end stage renal disease (ESRD) encounter to align with the intent of the measure. Additionally, we propose to update the "Kidney Transplant" value set to remove coding related to kidney transplant donors as it

Category	Description
	would be appropriate for these patients to still be assessed for blood pressure control if diagnosed with essential hypertension. We propose to revise the eCQM Specifications guidance section to provide clarification that patient obtained blood pressure readings captured via non-digital devices are not acceptable for this measure as they may not provide an accurate reading and therefore do not meet the intent of the measure, as well as the addition of clarifying language for what suffices as an acceptable blood pressure reading. Additionally, we propose to update the initial patient population for the eCQM Specifications collection type to align with clarification for the timing of the hypertension diagnosis. We propose to update the MIPS CQMs Specifications, Medicare Part B Claims Measure Specifications, and CMS Web Interface Measure Specifications collection types denominator, denominator note, and denominator confirmation to align with clarification for the timing of the hypertension diagnosis. Additionally for the MIPS CQMs Specifications, the Medicare Part B Claims Measure Specifications, and the CMS Web Interface Measure Specifications collection types, we propose to update the instructions note, numerator note, and narrative guidance to better clarify acceptable blood pressure readings for the purposes of clinical quality action assessment and examples of low intensity or preventive procedures that would not preclude the use of a blood pressure reading from that day or the day prior. We propose to revise the denominator note for the MIPS CQMs Specifications collection type, the numerator note for the Medicare Part B Claims Measure Specifications collection type, and the denominator guidance for the CMS Web Interface Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component.

D.30 Use of High-Risk Medications in Older Adults

Category	Description
NQF # / eCQM NQF #:	0022/ N/A
Quality#:	238
CMS eCQM ID:	CMS156v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.
Substantive Change:	**The measure description is revised to read:** **For the eCQM Specifications collection type:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. Three rates are reported. 1. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. 2. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class, except for appropriate diagnoses. 3. Total rate (the sum of the two numerators divided by the denominator, deduplicating for patients in both numerators). **For the MIPS CQMs Specifications collection type:** Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. **Updated definition: For the eCQM Specifications collection type: Added:** Index prescription start date. The start date of the earliest prescription ordered for a high-risk medication during the measurement period. **The measure denominator exclusion is revised to read: For the eCQM Specifications collection type:** 1. Exclude patients who are in hospice care for any part of the measurement period. 2. Exclude patients receiving palliative care during the measurement period. **Updated logic and logic definitions: For the eCQM Specifications collection type: Removed:** the 90-day supply criterion to the non-benzodiazepine hypnotics. **Updated value set/coding: For the eCQM Specifications collection type:** **Added:** drug classes methscopeolamine and pyrilamine. **Removed:** drug class Diphenhydramine hydrochloride. **The measure numerator is revised to read: For the eCQM Specifications collection type:** Rate 1: Patients with at least two orders of the same high-risk medication to avoid from the same drug class. Rate 2: Patients with at least two orders of high-risk medications from the same medication class (i.e., antipsychotics and benzodiazepines), except for appropriate diagnoses. Total rate (the sum of the two previous numerators, deduplicated). **Updated numerator exclusion: For the eCQM Specifications collection type: Added:** Rate 2: For patients with two or more antipsychotic prescriptions ordered, exclude patients who did have a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the Index Prescription Start Date (IPSD) for antipsychotics. For patients with two or more benzodiazepine prescriptions ordered, exclude patients who did have a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines. **Updated instructions: For the MIPS CQMs Specifications collection type:** **Added:** This measure will be calculated with 2 performance rates: 1. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class. 2. Percentage of patients 65 years of age and older who were ordered at least two high-risk medications from the same drug class, except for appropriate diagnoses. For accountability reporting in the CMS MIPS program, the rate for submission criteria 1 is used for performance. **The measure denominator is revised to read: For the MIPS CQMs Specifications collection type:** SUBMISSION CRITERIA 1: PERCENTAGE OF PATIENTS 65 YEARS OF AGE AND OLDER WHO WERE ORDERED AT LEAST TWO HIGH-RISK MEDICATIONS FROM THE SAME DRUG CLASS Denominator (Submission Criteria 1): Patients 65 years and older who had a visit during the measurement period SUBMISSION CRITERIA 2: PERCENTAGE OF PATIENTS 65 YEARS OF AGE AND OLDER WHO WERE ORDERED AT LEAST TWO HIGH-RISK MEDICATIONS FROM THE SAME DRUG CLASS, EXCEPT FOR APPROPRIATE DIAGNOSES Denominator (Submission Criteria 2): Patients 65 years and older who had a visit during the measurement period **Updated denominator criteria: For the MIPS CQMs Specifications collection type: Added:** Submission Criteria 2 Denominator Criteria: Patient aged ≥ 65 years on date of encounter. Patient encounter during performance period (in alignment with submission criteria 1). Denominator exclusions for hospice and palliative care during the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications collection type: Added:** Submission Criteria 1: Patients receiving palliative care during the measurement period.

Category	Description
	The measure numerator is revised to read: For the MIPS CQMs Specifications collection type: Numerator (Submission Criteria 1): Patients ordered at least two high-risk medications from the same drug class during the measurement year. Numerator (Submission Criteria 2): Patients with at least two orders of high-risk medications from the same drug class (i.e., antipsychotics and benzodiazepines), except for appropriate diagnoses. **Updated numerator definition: For the MIPS CQMs Specifications collection type: Revised:** Numerator (Submission Criteria 1): Definitions: The intent of the measure is to assess if the eligible clinician ordered high-risk medication(s).The intent of the numerator is to assess if the patient has either been ordered: • At least two high-risk medications from the same drug class (grouped by row) in Table 1 on different dates of service, or • At least two high-risk medications from the same drug class (grouped by row) in Table 2 on different dates of service, where the sum of days supply exceeds 90 days If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the submitting provider also ordered a high-risk medication for them from the same drug class. Cumulative Medication Duration – an individual's total number of medication days over a specific period; the period counts multiple prescriptions with gaps in between, but does not count the gaps during which a medication was not dispensed. To determine the cumulative medication duration, determine first the number of the Medication Days for each prescription in the period: the number of doses divided by the dose frequency per day. Then add the Medication Days for each prescription without counting any days between the prescriptions. For example, there is an original prescription for 30 days with 2 refills for thirty days each. After a gap of 3 months, the medication was ordered again for 60 days with 1 refill for 60 days. The cumulative medication duration is (30 x 3) + (60 x 2) = 210 days over the 10 month period. Table 1 - High-Risk Medications at any dose or duration: **Removed:** Orphenadrine from Anticholinergics, first-generation antihistamines **Revised:** Antithrombotics – Dipyridamole, oral short-acting **Added:** Nonbenzodiazepine hypnotics – Eszopiclon, Zolpidem, Zaleplon Table 2 - High-Risk Medications With Days Supply Criteria **Removed:** Nonbenzodiazepine hypnotics **Added:** Numerator (Submission Criteria 2): Definitions: The intent of the numerator is to assess if the patient has been ordered at least two high-risk medications form the same drug class (grouped by row) in Table 3 on different dates or service. The intent of the measure is to assess if the submitting provider ordered the high-risk medication(s). If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the submitting provider also ordered a high-risk medication for them from the same drug class. Index Prescription Start Date - the start date of the earliest prescription ordered for a high-risk medication during the measurement period. Table 3 - High-Risk Medications: Antipsychotics, first (conventional) and second (atypical) generation and Benzodiazepines, long, short, and intermediate acting. **Updated numerator instructions: For the MIPS CQMs Specifications collection type: Added:** Submission Criteria 2: INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The "Performance Not Met" numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control. A high-risk medication is identified by: • A prescription for medications classified as high risk at any dose and for any duration listed in Table 3 **Updated numerator note: For the MIPS CQMs Specifications collection type: Removed:** numerator note. **Updated numerator options: For the MIPS CQMs Specifications collection type: Revised:** Submission Criteria 1: **Performance Met:** At least two orders for high-risk medications from the same drug class **Performance Not Met:** At least two orders for high-risk medications from the same drug class not ordered **Added:** Submission Criteria 2: **Performance Met:** At least two orders for high-risk medications from the same drug class **Performance Not Met:** At least two orders for high-risk medications from the same drug class not ordered **Performance Not Met:** Two or more antipsychotic prescriptions ordered for patients who had a diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder on or between January 1 of the year prior to the measurement period and the Index Prescription Start Date (IPSD) for antipsychotics **Performance Not Met:** Two or more benzodiazepine prescriptions ordered for patients who had a diagnosis of seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, or severe generalized anxiety disorder on or between January 1 of the year prior to the measurement period and the IPSD for benzodiazepines

Category	Description
	Updated measure analytic: For all collection types: Revised: performance rate 1 will be utilized for benchmarking purposes.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to restructure all of the collection types to introduce new performance rates based upon the American Geriatric Society Beers Criteria and expert panel recommendations, with performance rate one being utilized for benchmarking purposes as it is more comprehensive in assessment and aligns across the collection types. These revisions allow for the inclusion of antipsychotics and benzodiazepines to ensure alignment with most recent recommendations. The description for the measure is being updated for all collection types to align with the revisions in the measure and reflect the restructuring within multiple components of the specifications. Additionally, there will be multiple performance rates: three performance rates for the eCQM Specifications collection type and two performance rates for the MIPS CQMs Specifications collection type. We propose that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. For the eCQM Specifications collection type, the term 'overlaps' was removed and replaced with plain language for clarity and consistency in implementation. The eCQM Specifications collection type's value sets were revised to add and remove drug classes and the logic for the non-benzodiazepine hypnotics was revised to remove the 90-day supply criterion to align with the American Geriatric Society Beers Criteria guidelines. We propose to revise the MIPS CQMs Specifications collection type to add a second performance rate and submission criteria as the measure is restructured to align with the American Geriatric Society Beers Criteria guidelines. Additionally, the medication tables have been revised to align with the current guidelines and intent of the measure revisions. Multiple components of the MIPS CQMs Specifications collection type were updated to align with revised structure and the American Geriatric Society Beers Criteria guidelines to ensure consistent language throughout and alignment with the measure intent.

D.31 Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	239
CMS eCQM ID:	CMS155v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. • Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. • Percentage of patients with counseling for nutrition. • Percentage of patients with counseling for physical activity.
Substantive Change:	**The measure title is revised from 'Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents' to:** Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents **Updated denominator exclusion: Revised:** Exclude patients who are in hospice care for any part of the measurement period. **Updated value set/coding: Revised:** "Pregnancy" (2.16.840.1.113883.3.526.3.378) value set to more accurately capture pregnancy state.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the title for alignment across programs. We propose to update the "Pregnancy" value set to more accurately capture the state of pregnancy to ensure the denominator exclusion is being applied to the correct patient population and remove the term 'overlaps' and replace with plain language for clarity and consistency in implementation.

D.32 Childhood Immunization Status

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	240
CMS eCQM ID:	CMS117v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.
Substantive Change:	**The measure denominator exclusion is revised to read:** Exclude patients who are in hospice care for any part of the measurement period. **The measure guidance is revised to read:** Numerator criteria includes evidence of receipt of the recommended vaccine or the following: -- DTaP: Adverse reaction to the DTaP or Td vaccine; or encephalopathy due to DTaP or Td vaccination -- Polio (IPV) vaccine: Adverse reaction to the IPV vaccine, streptomycin, polymyxin B, or neomycin -- MMR Vaccination: Immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; history of measles, mumps, or rubella; or a seropositive result for the antigens -- Hib: Adverse reaction to the Hib vaccine -- Hepatitis B: Seropositive result for the antigen, adverse reaction to the hepatitis B vaccine, adverse reaction to common baker's yeast, or a history of hepatitis B illness -- Chicken pox (varicella zoster): Seropositive result for the antigen; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; adverse reaction to neomycin; or a history of varicella zoster -- Pneumococcal: Adverse reaction to the pneumococcal vaccine -- Hepatitis A: Seropositive result for the antigen, adverse reaction to the hepatitis A vaccine, or a history of hepatitis A illness -- Rotavirus: Adverse reaction to the rotavirus vaccine, severe combined immunodeficiency, or a history of intussusception -- Influenza: Adverse reaction to the influenza vaccine; immunodeficiency, HIV, lymphoreticular cancer, multiple myeloma, or leukemia; or adverse reaction to neomycin The measure allows a grace period by measuring compliance with these recommendations between birth and age two. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated logic and logic definitions: Added:** influenza LAIV vaccination as numerator compliant.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. The measure guidance is updated to reflect the intent of the measure and clarify the criteria for numerator compliance more accurately. Additionally, we propose to update the logic and logic definitions to include the influenza LAIV vaccination to align with current clinical guidelines.

D.33 Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	254
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **Updated denominator criteria: Revised:** Patient has any emergency department encounter during the performance period with Place of Service Indicator 23 (The claim form Place of Service field must indicate emergency department) OR Patient encounter during the performance period (CPT)
Steward:	American College of Emergency Physicians
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator criteria to capture all patients with an encounter with a Place of Service indicator 23 to ensure that all applicable patients are being assessed for the quality action as it is appropriate for those patients who meet all other denominator criteria and are seen at any emergency department encounter. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.

D.34 Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Substantive Change:	**The measure denominator note is revised to read:** *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for MIPS CQMs. Only the first biopsy results for new patients should be reported for this measure. Do not include specimens sent for debridement.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator note to clarify which biopsy, if multiple biopsies are performed, should be utilized for assessment of the clinical quality action and that only new patients should be reported for the purposes of this measure.

D.35 Dementia: Cognitive Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 2872e
Quality#:	281
CMS eCQM ID:	CMS149v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**Updated logic and logic definitions: Revised:** dementia and qualifying encounter logic to clarify timing of during the measurement period.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the technical definition names and logic to provide clarity and ensure alignment with measure intent.

D.36 Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months
Substantive Change:	**The measure title is revised from 'Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease' to:** Assessment of Mood Disorders and Psychosis for Patients with Parkinson's Disease. **The measure description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period. **Updated denominator criteria: Removed:** coding related to Hospital Inpatient Services. **The measure numerator is revised to read:** Patients who were assessed for depression, anxiety, apathy, AND psychosis once during the measurement period. **The measure numerator definition is revised to read:** Assessed – use of a screening tool or discussion with the patient or care partner. Please see "Opportunity for Improvement" section below for suggestions on possible screening tools. Psychosis: includes hallucinations, illusions, delusions, paranoia **Updated numerator instructions:** **Added:** For Depression: Patient Health Questionnaire 2 (PHQ2), Patient Health Questionnaire 9 (PHQ9), Montgomery-Asberg Depression Rating Scale (MADRS) For Anxiety: Parkinson Anxiety Scale (PAS) **Removed:** For Impulse Control Disorder (9): Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease-Rating Scale (QUIP-RS) Minnesota Impulsive Disorders Interview **Updated numerator note: Removed:** the Numerator Note. **The measure numerator options are revised to read:** **Performance Met:** Depression, anxiety, apathy, AND psychosis assessed **Performance Not Met:** Depression, anxiety, apathy, AND psychosis not assessed
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure to lessen the requirements necessary for numerator compliance to balance quality patient care and clinician burden based upon feedback and recommendations from the measure steward's expert work group. The measure title, description, numerator, and numerator options will have updates to align with the proposed change to the measure's clinical quality action requirement. We propose to remove Hospital Inpatient Services from the denominator criteria as patients seen in the inpatient setting are not appropriate for inclusion within the denominator eligible patient population for the clinical quality action being assessed, as this is to address care for patients seen during outpatient encounters. Additionally, we propose to revise the numerator definition to more clearly define what "assessed" means for the purposes of this measure and what components are included within the term "psychosis". We propose to revise the list of tools available for use in the Parkinson's disease patient population to align with current availability and applicability. We propose to remove the numerator note to align with the updated time frame to ensure annual assessment.

D.37 Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	291
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months.
Substantive Change:	**The measure title is revised from 'Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease' to:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease. **The measure description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once during the measurement period. **Updated denominator criteria: Removed:** coding related to Hospital Inpatient Services. **The measure numerator is revised to read:** Patients (or care partner as appropriate) who were assessed for cognitive impairment or dysfunction once during the measurement period. **The measure numerator definition is revised to read:** Assessed – Is defined as a discussion with the patient or care partner or use of a screening tool OR referral to neuropsychologist for testing. **Updated numerator instructions: Added:** Neuro-QoL and Patient-Reported Outcomes Measurement Information System (PROMIS). **Updated numerator note: Removed:** the Numerator Note. **Updated numerator options: Added:** **Denominator Exception:** Patient or care partner decline assessment **Denominator Exception:** On date of encounter, patient is not able to participate in assessment or screening, including non-verbal patients, delirious, severely aphasic, severely developmentally delayed, severe visual or hearing impairment and for those patients, no knowledgeable informant available.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure's title to remove redundancy in wording. We propose to remove Hospital Inpatient Services from the denominator criteria as patients seen in the inpatient setting are not appropriate for inclusion within the denominator eligible patient population for the clinical quality action being assessed, as this is to address cares for patients seen during outpatient encounters. We propose to update the measure numerator and numerator definition to include the care partner within the assessment of the clinical quality action as patients who have severe cognitive impairment may be unable to accurately respond to questions, leaving clinicians to rely on care partners for accurate information. We propose to add the PROMIS and Neuro-QoL (Quality of Life) to the list of tools in the numerator instructions as these are applicable to the intent of the measure. Additionally, we propose to update the numerator options to add denominator exceptions as the measure steward's expert work group felt it was important not to penalize clinicians for patients/care partners who are unable to participate in or decline the assessment. Additionally, we propose to update the description and numerator to reflect that the quality action should be completed annually to ensure timely capture of cognitive impairment or dysfunction. To align with these revisions, we propose to remove the numerator note.

D.38 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months.
Substantive Change:	**The measure title is revised from 'Parkinson's Disease: Rehabilitative Therapy Options' to: Rehabilitative** Therapy Referral for Patients with Parkinson's Disease. **The measure description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease who were referred to physical, occupational, speech, or recreational therapy once during the measurement period. **Updated denominator criteria: Added:** Physical and Occupational Therapy, Speech Language Pathology **The measure numerator is revised to read**: Patients who were referred to physical, occupational, speech, or recreational therapy once during the measurement period. **Updated numerator note: Removed:** the Numerator Note. **The measure numerator options is revised to read:** **Performance Met:** Referral to physical, occupational, speech, or recreational therapy **Denominator Exception:** Patient and/or care partner decline referral **Denominator Exception:** Clinician determines patient does not require referral **Denominator Exception:** Patient already receiving physical/occupational/speech/recreational therapy during the measurement period **Performance Not Met:** Patient not referred, reason not otherwise specified
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure title to remove redundancy in wording. We propose to update the measure description and numerator to include recreational therapy as it is clinically relevant and can be beneficial to the Parkinson's disease patient population. We propose to update and expand the denominator coding to include additional MIPS eligible clinician types as this measure may be appropriate to their scope of care. We propose to remove the numerator note to align with the updated time-frame to ensure annual assessment. Additionally, we propose to update the numerator options to align with the addition of recreational therapy as numerator compliant and allowing for denominator exceptions for those patients that decline a referral, do not need a referral based on the stage of the disease, or for those patients who are already receiving one or more of the services, as clinicians should not be penalized in these situations.

D.39 Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	305
CMS eCQM ID:	CMS137v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. b. Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.
Substantive Change:	**The measure denominator exclusion is revised to read:** 1. Exclude patients with a negative diagnosis history, defined as an encounter or medication treatment for a diagnosis of alcohol, opioid or other drug abuse or dependence in the 60 days prior to the first episode of alcohol or drug dependence. 2. Exclude patients who are in hospice care for any part of the measurement period. **Updated initial patient population: Revised:** logic for timing associated with the timing of the first dependence diagnosis. **Updated numerator logic: Revised:** timing attribute associated with orders of medications to 'authorDatetime'. **The measure stratification is revised to read:** Report a total score, and each of the following strata: Stratum 1: Patients age 13-17 at the start of the Measurement Period Stratum 2: Patients age >=18 at the start of the Measurement Period
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion to more accurately represent the intent to exclude patients with prior and recent history of substance abuse treatment as this patient population is not appropriate for the clinical quality action being assessed. The term 'overlaps' was removed from the denominator exclusion and replaced with plain language for clarity and consistency in implementation. We propose to revise the logic for the timing associated with the first dependence diagnosis timing to align with the intent of the measure to correctly capture all diagnoses during the measurement period through November 14. We propose to update the datatype for "Medication, Order" to use 'authorDatetime' as this is the preferred timing attribute. We propose to revise the anchor for age calculations of the stratifications to align with those within the initial patient population for alignment.

D.40 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years
Substantive Change:	**Updated denominator exclusion:** **Revised:** Exclude patients who are in hospice care for any part of the measurement period. **Added:** Exclude patients receiving palliative care during the measurement period. **Updated value set/coding: Updated:** replaced "Congenital absence of cervix (disorder)" ("SNOMEDCT Code (37687000)") with "Congenital or Acquired Absence of Cervix" (2.16.840.1.113883.3.464.1003.111.12.1016) value set.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language be updated for all collection types to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed and the term 'overlaps' was removed and replaced with plain language for clarity and consistency in implementation. We propose to update the value sets for the denominator exclusion to include acquired absence of cervix as this patient population is not appropriate for the clinical quality action being assessed.

D.41 Chlamydia Screening for Women

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	310
CMS eCQM ID:	CMS153v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.
Substantive Change:	**Updated denominator exclusion: Revised:** Exclude patients whose who are in hospice care for any part of the measurement period. **Updated value set: Added:** Clutton's joints "Diagnoses Used to Indicate Sexual Activity" value set.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the term 'overlaps' and replace with plain language for clarity and consistency in implementation. We propose to update the "Diagnoses Used to Indicate Sexual Activity" value set to align with coding utilized in other programs, however, this code set will undergo further refinements in future years.

D.42 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications | CMS Web Interface Measure Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type: Revised:** Exclude patients who are in hospice care for any part of the measurement period. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Removed:** Exclude patients who were assessed to be non-ambulatory during the measurement period. **Updated denominator guidance: For the CMS Web Interface Measure Specifications collection type: Removed:** Denominator Exclusion, count as non-ambulatory only if non-ambulatory at the most recent encounter during the measurement period (i.e., patient is not ambulatory, bed ridden, immobile, confined to chair, wheelchair bound, dependent on helper pushing wheelchair, independent in wheelchair or minimal help in wheelchair).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose for the eCQM Specifications collection type to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We proposed for the CMS Web Interface Measure Specifications collection type to remove the denominator exclusion for non-ambulatory patients to address implementation challenges as there is a lack of available documentation for a non-ambulatory status. Additionally, the denominator guidance has been updated to reflect this revision.

D.43 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
Quality#:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type. **The measure description is revised to read:** Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period. **Updated denominator exclusion: Added:** 1. Patients with moderate or severe mitral stenosis 2. Patients with mechanical prosthetic heart valve
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type. We propose to revise the measure description to align with the language revisions in the measure to no longer explicitly state the valve types. We propose to add denominator exclusions that align with language revisions to remove those patients for whom the clinical quality action being assessed would not be appropriate. In the circumstance the Medicare Part B Claims Measure Specifications collection type is not finalized for removal, all finalized substantive changes will be reflected within this collection type specification.

D.44 Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication.
Substantive Change:	**The measure title is revised from 'Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)' to:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) **The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period, delivered a live singleton at < 39 weeks of gestation, and had elective deliveries (without medical indication) by cesarean birth or induction of labor. **The measure numerator options are revised to read:** **Performance Met:** Elective delivery (without medical indication) by cesarean birth or induction of labor performed (<39 weeks of gestation) **Denominator Exception:** Medical indication for delivery by cesarean birth or induction of labor (<39 weeks of gestation) [Documentation of reason(s) for elective delivery (e.g., hemorrhage and placental complications, hypertension, preeclampsia and eclampsia, rupture of membranes (premature or prolonged), maternal conditions complicating pregnancy/delivery, fetal conditions complicating pregnancy/delivery, late pregnancy, prior uterine surgery, or participation in clinical trial)] **Performance Not Met:** Elective delivery (without medical indication) by cesarean birth or induction of labor not performed (<39 weeks of gestation) **Updated performance calculation: Revised:** Measure analytic was updated to be inverse.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the measure analytic to be inverse to better align with the intent of the measure as this is an overuse measure. We propose to update the measure title, description, and numerator options to align with the revision in analytic as a lower calculated performance rate will now indicate better clinical care for the purposes of this measure. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.45 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The measure description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. **The measure denominator is revised to read:** All patients, regardless of age, who gave birth during a 12-month period and were seen for postpartum care at a visit before or at 12 weeks of giving birth. **Updated denominator criteria: Revised:** Postpartum care visit before or at 12 weeks of giving birth. **Updated instructions:** This measure is to be submitted a minimum of once per performance period for all patients seen for postpartum care before or at 12 weeks of giving birth during the performance period. **Updated numerator definition: Revised:** to align with the measure change from 8 weeks to 12 weeks postpartum.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the timeframe for the postpartum care visit from before or at 8 weeks of giving birth to before or at 12 weeks of giving birth, which is reflected in revisions to multiple components of the measure for alignment. This revision aligns with American College of Obstetricians and Gynecologists (ACOG) guidance and better aligns with current clinical workflows. This also ensures a more complete patient population is addressed to drive quality care.

D.46 HIV Medical Visit Frequency

Category	Description
NQF # / eCQM NQF #:	2079 / N/A
Quality#:	340
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.
Substantive Change:	**The measure denominator note is revised to read:** In order to determine denominator eligibility, patients should be diagnosed with HIV during the first 3 months of the 24-month measurement period or have a diagnosis prior to the 24- month measurement period. The 24-month measurement period is defined as the 24 months prior to and including the date of the first qualifying encounter during the performance period (i.e., January 1, 2022 through December 31, 2022). Performance of the measure is met when there is at least one medical visit in each 6 month interval with 60 days between denominator eligible encounters for patients with HIV within the 24-month measurement period.
Steward:	Health Resources and Services Administration
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator note to clarify the 24-month period to ensure alignment with the measure intent and consistency in implementation.

D.47 Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	350
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.
Substantive Change:	**The measure title is revised from 'Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy' to:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy. **The measure description is revised to read:** Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision- making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure. **Updated instructions: Revised:** This measure is to be submitted each time a procedure for total knee or total hip replacement is performed during the performance period. **Updated denominator: Added:** Total hip replacement.
Steward:	American Association of Hip and Knee Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure to include total hip replacements as denominator eligible as the clinical quality action being assessed is applicable to this procedure as well. This will ensure that a broader patient population is being assessed as it is important to for the patient and clinician to engage in shared decision making to ensure that joint replacement therapy is the best treatment option. Multiple components of the measure will be updated to reflect the additional procedure of total hip replacement. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.48 Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	351
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).
Substantive Change:	**The measure title is revised from 'Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation' to:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation. **The measure description is revised to read:** Percentage of patients regardless of age undergoing a total knee or total hip replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke). **Updated instructions: Revised:** This measure is to be submitted each time a procedure for total knee or total hip replacement is performed during the performance period. **Updated denominator: Added:** Total hip replacement.
Steward:	American Association of Hip and Knee Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure to include total hip replacements as denominator eligible as the clinical quality action being assessed is applicable to this procedure as well. This will ensure that a broader patient population is being assessed as it is important to evaluate this patient population for venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure to ensure that joint replacement therapy is the best treatment option. Multiple components of the measure will be updated to reflect the additional procedure of total hip replacement. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.49 Patient-Centered Surgical Risk Assessment and Communication

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	358
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.
Substantive Change:	**Updated denominator criteria: Added:** Coding related to 'Ablation, irreversible electroporation; 1 or more tumors per organ'
Steward:	American College of Surgeons
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator criteria to add a procedure that is appropriate for the measure intent.

D.50 Follow-Up Care for Children Prescribed ADHD Medication (ADD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	366
CMS eCQM ID:	CMS136v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.
Substantive Change:	**Updated denominator exclusion: Revised:** For all denominators: Exclude patients who are in hospice care for any part of the measurement period. **The measure guidance is revised to read:** This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure numerator is revised to read:** Numerator 1: Patients who had at least one visit with a practitioner with prescribing authority within 30 days after the IPSD. Numerator 2: Patients who had at least one visit with a practitioner with prescribing authority during the Initiation Phase, and at least two follow-up visits during the Continuation and Maintenance Phase. **Updated performance calculation: Revised:** Performance Rate 2 will be used for benchmarking purposes.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We propose to update the guidance to remove the language regarding how cumulative medication duration is calculated as this is outdated and no longer in alignment with the measure intent. We propose to revise the numerator language to allow for telehealth visits as these are appropriate for inclusion when assessing for the clinical quality action. We propose to update the performance calculation for the measure to utilize the performance rate for submission criteria 2 as this is more indicative of quality care during and after the Initiation Phase. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.51 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Updated logic definitions: For the eCQM Specifications collection type: Revised:** timing of denominator exclusion elements; 'Global."ToDate" {element} on or before end of "Measurement Assessment Period". **Updated denominator criteria: For all collection types: Added:** coding for mental and behavioral health MIPS eligible clinicians to both submission criteria. **Updated initial population: For the CMS Web Interface Measure Specifications collection type: Revised:** Adolescent patients 12 to 17 years of age and adult patients 18 years of age and older with a diagnosis of major depression or dysthymia and an initial Patient Health Questionnaire-9 item version (PHQ-9) or Patient Health Questionnaire-9 Modified for Teens and Adolescents (PHQ-9M) score greater than nine during the index event. Patients may be assessed using PHQ-9 or PHQ-9M on the same date or up to 7 days prior to the encounter (index event). **Updated guidance: For the CMS Web Interface Measure Specifications collection type: Added:** When a baseline assessment is conducted with PHQ 9M, the follow-up assessment can use either a PHQ 9M or PHQ 9. **Updated denominator exclusion: For the CMS Web Interface Measure Specifications collection type: Added:** Patients with a diagnosis of personality disorder emotionally labile.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the eCQM Specifications collection type to revise the timing of the denominator exclusion elements to ensure the full 12 months + 60 days after the index event date is allowed in order to align with the measure intent and language. We propose to expand the denominator eligible encounters for all collection types to include mental and behavioral health MIPS eligible clinicians as this measure is applicable to their scope of care. We propose to update the CMS Web Interface Measure Specification collection type as the measure steward believes that allowing flexibility for the timeframe in which a PHQ-9/PHQ-9M can be obtained will accommodate pre-visit planning or distribution of a PHQ-9/PHQ-9M tool prior to the encounter (office visit, psychiatry or psychotherapy visit, telephone or online encounter). The intent of this change includes the following principles: (1) The patient must have the corresponding diagnosis at the time of the index encounter. (2) The patient must have completed the PHQ-9/PHQ-9M and have a score greater than 9. (3) That same PHQ-9/PHQ-9M is directly tied to and used during the index encounter. We propose to revise the denominator exclusion language for the CMS Web Interface Measure Specifications collection type for a diagnosis of personality disorder to further clarify ensuring the correct patient population is being excluded from quality action assessment. We propose to update the guidance for CMS Web Interface Measure Specifications collection type to add clarity regarding the assessment that may be used for the follow-up assessment for the purposes of meeting performance for this measure.

D.52 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v10
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Substantive Change:	**The measure numerator note is revised to read: For the MIPS CQMs Specifications collection type:** The consultant report that will successfully close the referral loop should be related to the first referral for a patient during the measurement period. If there are multiple consultant reports received by the referring provider which pertain to a particular referral, use the first consultant report to satisfy the measure. The provider to whom the patient was referred is responsible for sending the consultant report that will fulfill the communication. Note: this is not the same provider who would report on the measure.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator note for the MIPS CQMs Specification collection type to add clarifying language that the first referral for a patient should be utilized for the purposes of assessing whether the referral loop was closed and the clinical quality action completed, as this aligns with the intent of the measure.

D.53 Functional Status Assessment for Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	375
CMS eCQM ID:	CMS66v10
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Substantive Change:	**The measure denominator exclusion is revised to read:** 1. Exclude patients with two or more fractures indicating trauma at the time of the total knee arthroplasty or patients with severe cognitive impairment that starts before or in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period. **Updated value set/coding: Revised:** 'Primary TKA Procedure' (2.16.840.1.113883.3.464.1003.198.12.1007) value set to include revisions of one component of total prosthetic replacement of knee joint.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We propose to expand the 'Primary TKA Procedure' value set to include revisions of one component of total prosthetic replacement of knee joint to create a more complete denominator eligible patient population as completing a functional status assessment would be appropriate for this patient population.

D.54 Functional Status Assessment for Total Hip Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	376
CMS eCQM ID:	CMS56v10
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.
Substantive Change:	**The measure denominator exclusion is revised to read:** 1. Exclude patients with two or more fractures indicating trauma at the time of the total hip arthroplasty or patients with severe cognitive impairment that starts before or in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation.

D.55 Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v11
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**The measure title is revised from 'Functional Status Assessments for Congestive Heart Failure' to:** Functional Status Assessments for Heart Failure. **The measure description is revised to read:** Percentage of patients 18 years of age and older with heart failure who completed initial and follow-up patient-reported functional status assessments. **The measure denominator exclusion is revised to read:** 1. Exclude patients with severe cognitive impairment in any part of the measurement period. 2. Exclude patients who are in hospice care for any part of the measurement period. **The measure guidance is revised to read:** Initial functional status assessment (FSA) and encounter: The initial FSA is an FSA that occurs two weeks before or during an encounter, in the 180 days or more before the end of the measurement period. Follow-up FSA: The follow-up FSA must be completed at least 30 days but no more than 180 days after the initial FSA. The same FSA instrument must be used for the initial and follow-up assessment. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The measure initial patient population is revised to read:** Patients 18 years of age and older who had two outpatient encounters during the measurement period and a diagnosis of heart failure that starts before and continues into the measurement period. **Updated logic and logic definitions: Updated:** restructured the logic to ensure the patient meets the denominator criteria by 1) had multiple assessments in the year and that 2) there is sufficient time for them to have had repeat assessments in the year 3) there is sufficient time between assessments for their condition to have changed or for them to have responded to treatment (30-180days).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the term 'congestive' from the measure title and description based upon the expert work group recommendations in order to align the language with the denominator eligible patient population to ensure all appropriate patients are included in the initial patient population. We propose to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation. We propose to revise the measure guidance to aid in measure implementation, align with measure intent and the timing constraints within the logic of the measure. We propose to update the initial patient population to clarify timing of the heart failure diagnosis and ensure alignment with the logic. Additionally, we propose to revise the logic to more clearly reflect relationships between the encounter and assessment(s), as identifying the first encounter without ensuring a relationship with an assessment does not meet the intent of the measure.

D.56 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The measure description is revised to read:** Percentage of children, 6 months - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period **The measure denominator exclusion is revised to read:** Exclude patients who are in hospice care for any part of the measurement period. **The measure numerator is revised to read:** Children who had a diagnosis of cavities or decayed teeth in any part of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the measure description to be more explicit of the timing associated with the patient's age. We propose to remove the term 'overlaps' from the denominator exclusion and numerator and replace with plain language for clarity and consistency in implementation.

D.57 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v11
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The measure denominator exclusion is revised to read:** Exclude patients who are in hospice care for any part of the measurement period
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the term 'overlaps' from the denominator exclusion and replace with plain language for clarity and consistency in implementation.

D.58 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
NQF # / eCQM NQF #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator criteria: Added:** Filled at least two prescriptions for any of the qualifying antipsychotic medications listed under "Denominator Note" during the performance period **Added:** outpatient mental health encounters ocurring at federally qualified health centers for the 'Patient encounter during the performance period determination Outpatient Setting Option 1'. **Updated denominator note: Added:** lumateperone to 'Atypical Antipsychotic Medications'
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to add denominator criteria to ensure that only those patients who fill at least two prescriptions for any of the qualifying antipsychotic medications are included within the denominator eligible patient population as this aligns with the intent of the measure and protects clinicians from being held accountable for non-established patients. We propose to add outpatient mental health encounters ocurring at FQHCs as denominator eligible as schizophrenia may be diagnosed at these encounters. This revision is not a reflection of any policy update and was made to allow those clinicians who bill exclusively through a FQHC to track their performance on the measure. This payment method is still not eligible for payment adjustments under MIPS. We propose to update the 'Atypical Antipsychotic Medications' to align with current Food and Drug Administration (FDA) approved treatments for adults with schizophrenia.

D.59 Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576 / N/A
Quality#:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**The measure description is revised to read:** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health provider. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge • The percentage of discharges for which the patient received follow-up within 7 days after discharge
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the description to utilize the term provider in place of practitioner for alignment within the specification.

D.60 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	395
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.
Substantive Change:	**The measure description is revised to read: For all collection types:** Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report. **The measure numerator is revised to read: For all collection types:** Lung biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following IASLC guidance (see below) (including but not limited to squamous cell carcinoma or adenocarcinoma) OR classified as NSCLC-NOS with an explanation included in the pathology report IASLC Guidance: The IASLC recommends the following regarding terminology for small biopsy and cytology specimens: 1. Do not use the term "large cell carcinoma" 2. Do not use the term "AIS (adenocarcinoma in situ)" or "MIA (minimally invasive adenocarcinoma)"—if a noninvasive pattern is present in a small biopsy, the term "lepidic growth" should be used instead 3. Do not use the term "BAC (bronchioloalveolar carcinoma)" All three recommendations must be followed in order for a case to be considered Met (ie if any one of these terms is present, the case is Not Met) **The measure numerator options are revised to read: For all collection types:** **Performance Met:** Primary non-small cell lung cancer lung biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC- NOS with an explanation **Denominator Exception:** Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation (e.g. Specimen insufficient or non-diagnostic, specimen does not contain cancer, or other documented medical reasons) **Performance Not Met:** Primary non-small cell lung cancer lung biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description to add clarity in alignment with the measure intent. We propose to update the numerator and numerator options to add guidance regarding what phrases should be avoided within the pathology reports to align with IASLC guidance and to clarify what is acceptable for numerator compliance.

D.61 Lung Cancer Reporting (Resection Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	396
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.
Substantive Change:	**The measure description is revised to read: For all collection types:** Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure description to include the term 'lung' for clarity and alignment within the specification.

D.62 Melanoma Reporting

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	397
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.
Substantive Change:	**The measure description is revised to read: For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors. **The measure instructions are revised to read: For all collection types:** This measure is to be submitted each time a patient's pathology report addresses specimens with a diagnosis of malignant cutaneous melanoma; however, only one quality-data code (QDC) per date of service for a patient is required. In instances where multiple specimens from different/unique lesions are submitted and resulted in a single report, each eligible specimen must be Met in order for the case to be considered Met (Denominator Exclusions and Denominator Exceptions are not considered eligible specimens). If any eligible specimen is Not Met, the quality data code for Not Met should be submitted for this report. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The measure numerator is revised to read: For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the pT category thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors **The measure numerator options are revised to read: For all collection types:** **Performance Met:** Pathology report includes the pT Category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors **Denominator Exception:** Documentation of medical reason(s) for not including pT Category,thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors (e.g., negative skin biopsies, insufficient tissue, or other documented medical reasons) **Performance Not Met:** Pathology report does not include the pT Category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure for all collection types to require to new data elements for numerator compliance to align with updated American Academy of Dermatology (AAD) guideline recommendations. This revision is reflected in the proposed description, numerator, and numerator options language revisions to ensure the measure is aligned with the current clinical recommendations. Additionally, we propose to revise the instructions for all collection types to clarify how to handle instances where there are multiple samples included within one report.

D.63 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	400
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.
Substantive Change:	**The measure title is revised from 'One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk' to:** One-Time Screening for Hepatitis C Virus (HCV) for all Patients. **The measure description is revised to read:** Percentage of patients age >= 18 years who received one-time screening for hepatitis C virus (HCV) infection **The measure instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients > =18 years of age seen during the performance period AND who were seen twice for any visits or who had at least one preventive visit within the 12-month performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The measure denominator is revised to read:** All patients >= 18 years of age who had at least one preventive visit OR were seen at least twice within the 12-month reporting period. **Updated denominator criteria: Removed:** Patients who were born in the years 1945 to 1965 OR History of receiving blood transfusions prior to 1992 OR Receiving maintenance hemodialysis (CPT) OR History of injection drug use
Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update this measure to align with current clinical recommendations which no longer require at-risk conditions for HCV screening. The measure will be updated to require one-time HCV screening for all patients aged 18 years and older, in accordance with current clinical recommendations. We propose to revise the measure title, description, instructions, and denominator to reflect the removal of the at-risk criteria. Additionally, we propose to remove the at-risk criteria from the denominator criteria. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.64 Clinical Outcome Post Endovascular Stroke Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	409
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.
Substantive Change:	**The measure description is revised to read:** Percentage of patients with a Modified Rankin Score (mRS) score of 0 to 2 at 90 days following endovascular stroke intervention. **Updated instructions: Revised:** This measure is to be submitted a minimum of once per performance period for patients undergoing an endovascular stroke intervention procedure during the performance period. This measure is intended to reflect the success of the endovascular intervention inclusive of appropriate patient selection. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure- specific denominator coding. Include only patients that have cerebrovascular accidents through September 18 of the performance period. This will allow the evaluation of clinical outcome 90 days after the cerebrovascular accident within the performance period. Assessment of the mRS between 75 and 105 days is considered acceptable for reporting this measure. **Added:** Unique to this measure is the Minimum Process of Care Performance Threshold Requirement. This measure based threshold requires that at least 90% of all eligible patients have an mRS score assessed 90 days following endovascular stroke intervention. Therefore, if the performance rate for Submission Criteria 1 is below 90%, the MIPS eligible clinician would not be able to meet the denominator of the Submission Criteria 2 and this measure CANNOT BE SUBMITTED. CMS anticipates the performance rate for Submission Criteria 2 will be calculated using 100% of patients that met performance in Submission Criteria 1. This measure contains two submission criteria which together measure the outcome following an endovascular stroke intervention. Submission Criteria 1 evaluates whether an appropriate percentage of patients received the applicable clinical follow-up assessment using mRS. Submission Criteria 2 evaluates the rate of achieving an mRS score of 0 to 2 in those patients for whom an mRS score was obtained (during clinical follow-up, Submission Criteria 1). The rate of achieving an mRS of 0 to 2 at 90 days (Submission Criteria 2) can be used to compare this measure to performance prior to the 2021 performance year, when the measure had a single performance rate. For accountability reporting in the CMS MIPS program, the rate for Submission Criteria 2 is used for performance. For the purposes of submitting this measure Data Completeness has been determined in Submission Criteria 1. THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) Percentage of patients with mRS score assessed at 90 days following endovascular stroke intervention AND 2) Percentage of patients with mRS score of 0 to 2 assessed at 90 days following endovascular stroke intervention **Updated denominator: Revised:** **Submission Criteria 1:** Percentage of patients with clinical follow-up and mRS score assessed at 90 days following endovascular stroke intervention. **Denominator (Submission Criteria 1):** All patients with CVA undergoing endovascular stroke treatment. **Submission Criteria 2**: Percentage of patients with Performance Met for Submission Criteria 1 with an mRS score of 0 to 2 assessed at 90 days following endovascular stroke intervention therapy. **Denominator (Submission Criteria 2):** Patients with Performance Met for Submission Criteria 1 who received clinical follow-up and mRS score assessed at 90 days following endovascular stroke intervention therapy. **Updated denominator criteria: Revised:** Denominator (Submission Criteria 1) • All patients • Diagnosis for ischemic stroke • Patient procedure (endovascular stroke treatment) Denominator (Submission Criteria 2) • Minimum Process of Care Threshold Requirement: At least 90% of all eligible patients had an mRS score assessed at 90 days following endovascular stroke intervention (GXXXX submitted for Submission Criteria 1) **Updated numerator: Revised:** **Numerator (Submission Criteria 1):** Patients who received clinical follow-up and mRS score assessed at 90 days. **Numerator (Submission Criteria 2):** Patients with Performance Met for Submission Criteria 1 with 90 day mRS score of 0-2. **Updated numerator note: Added:** For the purposes of submitting this measure Data Completeness has been determined in Submission Criteria 1. The performance rate calculated for Submission Criteria 2 of this measure is calculated using the subset of patients identified in the Performance Met Numerator Option of Submission Criteria 1 (GXXXX). **Updated numerator options:** **Added:** Numerator Options (Submission Criteria 1): **Performance Met:** Clinical follow-up and mRS score assessed at 90 days following endovascular stroke intervention **Performance Not Met:** Clinical follow-up and mRS score not assessed at 90 days following endovascular stroke intervention **Revised:** Numerator Options (Submission Criteria 2): **Performance Met:** Patients with 90 day mRS score of 0 to 2

Category	Description
	Performance Not Met: Patients with 90 day mRS score greater than 2
Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose an update to the measure that includes a new submission criterion to assess whether a clinical follow-up and mRS score is being completed post endovascular stroke treatment. Additionally, this new submission criterion will ensure that the denominator eligible patient population being assessed for an mRS score of 0 – 2 is representative of the assessed population post treatment to determine the degree of disability or dependence in daily activities for patient suffering stroke. We propose to add an additional denominator criterion for submission criteria 2 that requires a 'Minimum Process of Care Threshold Requirement' of 90%. This ensures that patients are receiving post treatment follow-ups as a standard of care being and assessed for good outcomes following a stroke. This update is reflected with the restructure of multiple components of the specification to ensure clarity on the implantation of the measure change. We also propose to update the measure instructions to clarify what timeframe constitutes the 90-day follow-up and to align with the revisions to add a submission criterion. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for creation of a performance period benchmark, a new benchmark will be used for scoring.

D.65 Door to Puncture Time for Endovascular Stroke Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	413
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.
Substantive Change:	**The measure description is revised to read:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of 90 minutes or less **The measure numerator is revised to read:** Patients with CVA undergoing endovascular stroke treatment who have a door to puncture time of less than 90 minutes **Updated numerator options: Revised:** To align with door to puncture time of 90 minutes or less.
Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to revise the measure to reflect an updated door to puncture time of 90 minutes or less to more closely align with Target Stroke (a national initiative organized by the American Heart Association/American Stroke Association) which has an initial goal of achieving a door-to-puncture time of no more than 60 minutes for at least 50 percent of acute ischemic stroke patients. Additionally, The Joint Commission has set an ambitious goal of 80 percent of patients treated within 1 hour for primary stroke centers. This revision will drive quality care for this patient population as every delay in time from onset to arterial puncture will result in significant decreases in likelihood of a good outcome.

D.66 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated numerator options: For all collection types: Added:** **Performance Met:** Pediatric patient with minor blunt head trauma and PECARN prediction criteria are not assessed.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to add a Performance Met numerator option to this measure to ensure those patients without a documented PECARN prediction score are correctly submitted as a Performance Met. As the PECARN prediction should be assessed for all patients seen for minor blunt head trauma, those patients without a documented PECARN predication score would not meet the intent of the measure.

D.67 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
Quality#:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**The measure description is revised to read: For all collection types:** The percentage of women 50–85 years of age who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the six months after the fracture. **Updated denominator note: For the MIPS CQMs Specifications collection type: Added:** To assess the age for exclusions, the patient's age at the end of the measurement period should be used. **Updated denominator exclusion: For all collection types:** **Added:** Patients who receive palliative care services any time during the intake period through the end of the measurement year **Added:** Donzepezil-memantine to Dementia medication list. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type: Added:** To assess the age for exclusions, the patient's age on the date of the encounter should be used.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the description for alignment with other programs. We propose that the denominator exclusion language be updated to add an exclusion for patients receiving palliative care, as this patient population is not appropriate for the clinical quality action being assessed. Additionally, the medications were update for the Dementia medication list to include Donzepezil-memantine as this is an applicable medication for the purposes of the denominator exclusion. We propose to revise the denominator note for the MIPS CQMs Specifications collection type and the numerator note for the Medicare Part B Claims Measure Specifications collection type to clarify the timing for those exclusions that have an age-related component.

D.68 Photodocumentation of Cecal Intubation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	425
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.
Substantive Change:	**Modified collection type:** MIPS CQM Specifications collection type
Steward:	American Society for Gastrointestinal Endoscopy
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped-out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.

D.69 Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	430
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Substantive Change:	**Updated numerator definition: Added:** Propofol for induction and maintenance of anesthesia
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the numerator definition to add propofol as this is a commonly used prophylactic antiemetic and aligns with current clinical recommendations.

D.70 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v5
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications | CMS Web Interface Measure Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: *All patients who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR *Patients aged >= 20 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR *Patients aged 40-75 years with a diagnosis of diabetes **The measure definition is revised to read: For the eCQM Specifications collection type:** Clinical atherosclerotic cardiovascular disease (ASCVD) includes: * Acute coronary syndromes * History of myocardial infarction * Stable or unstable angina * Coronary or other arterial revascularization * Stroke or transient ischemic attack (TIA) * Peripheral arterial disease of atherosclerotic origin Lipoprotein density cholesterol (LDL-C) result: * A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available on the same day, the direct LDL-C test result should be used. Statin therapy: * Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Statin Medication Therapy List (NOTE: List does NOT include dosage): [Generic name] (Brand or trade name) and (-) Medication type, if applicable: [Atorvastatin] (Lipitor) - Statin [Fluvastatin] (Lescol XL or Lescol) - Statin [Lovastatin (Mevinolin)](Mevacor or Altoprev) -Statin [Pitavastatin] (Livalo or Zypitamag or Nikita) - Statin [Pravastatin Sodium] (Pravachol) - Statin [Rosuvastatin Calcium] (Crestor) - Statin [Simvastatin] (Zocor) - Statin [Amlodipine Besylate/Atorvastatin Calcium] (Caduet) – Fixed Dose Combination [Ezetimibe/Simvastatin] (Vytorin) – Fixed Dose Combination Statin-Associated Muscle Symptoms (SAMS) – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. **Updated denominator exception:** **For the eCQM Specifications CMS Web Interface Measure Specifications collection types:** **Revised:** Patients with statin-associated muscle symptoms or an allergy to statin medication **Removed:** Patients with diabetes who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and are not taking statin therapy **For the MIPS CQM Specifications collection type:** **Revised:** Documentation of medical reason(s) for not currently being a statin therapy user or receiving an order (prescription) for statin therapy (e.g., patients with statin-associated muscle symptoms or an allergy to statin medication therapy, patients who are receiving palliative or hospice care, patients with active liver disease or hepatic disease or insufficiency, and patients with end stage renal disease [ESRD]) **Removed:** Submisstion Criteria Three: Documentation of patients with diabetes who have a most recent fasting or direct LDL-C laboratory test result < 70 mg/dL and are not taking statin therapy **Updated denominator exclusion: For all collection types: Added:** Timeframe of 'at any time during the measurement period' to all denominator exclusions. **The measure guidance is revised to read: For the eCQM Specifications collection type:** Initial Population Guidance: The initial population covers three distinct populations. Use the following process to prevent counting patients more than once. Initial Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure, before the end of the measurement period.

Category	Description
	-If YES, meets Initial Population 1 risk category -If NO, screen for next risk category Initial Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory test result of LDL-C >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia -If YES, meets Initial Population 2 risk category -If NO, screen for next risk category Initial Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with an active diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period -If YES, meets Initial Population 3 risk category -If NO, patient does NOT meet Initial Population criteria and is NOT eligible for measure inclusion Initial Population Guidance for Encounter: -In order for the patient to be included in the Initial Population, the patient must have ONE initial population-eligible visit, defined as follows: outpatient visit, initial or established office visit, face-to-face interaction, preventive care services, or annual wellness visit. LDL-C Laboratory test result options: The measure can be reported for all patients with a documented LDL-C level recorded as follows: To meet Initial Population 1: There is no LDL-C result required. To meet Initial Population 2: If a patient has ANY previous laboratory result of LDL-C >= 190 mg/dL, report the highest value >= 190 mg/dL. To meet Initial Population 3: There is no LDL-C result required. Numerator instructions and guidance: -Current statin therapy use must be documented in the patient's current medication list or ordered during the measurement period. -ONLY statin therapy meets the measure Numerator criteria (NOT other cholesterol lowering medications). -Prescription or order does NOT need to be linked to an encounter or visit; it may be called to the pharmacy. -Statin medication "samples" provided to patients can be documented as "current statin therapy" if documented in the medication list in health/medical record. -Patients who meet the denominator criteria for inclusion, but are not prescribed or using statin therapy, will NOT meet performance for this measure unless they have an allowable denominator exception. Patients with an allowable denominator exception should be removed from the denominator of the measure and reported as a valid exception. -There is only one performance rate calculated for this measure: the weighted average of the three populations. -Adherence to statin therapy is not calculated in this measure. -It may not be appropriate to prescribe statin therapy for some patients (see exceptions and exclusions for the complete list) Intensity of statin therapy in primary and secondary prevention: The expert panel of the 2018 ACC/AHA/MS Guidelines (Grundy et al., 2019) defines recommended intensity of statin therapy on the basis of the average expected LDL-C response to specific statin and dose. Although intensity of statin therapy is important in managing cholesterol, this measure assesses prescription of ANY statin therapy, irrespective of intensity. Assessment of appropriate intensity and dosage documentation added too much complexity to allow inclusion of statin therapy intensity in the measure at this time. Lifestyle modification coaching: A healthy lifestyle is important for the prevention of cardiovascular disease. However, lifestyle modification monitoring and documentation added too much complexity to allow its inclusion in the measure at this time. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated guidance/denominator confirmation: For the CMS Web Interface Measure Specifications collection type: Revised:** Language within all of the guidance/confirmation sections was updated to reflect the changes to the initial patient poulations. **The measure initial patient population is revised to read: For the eCQM Specifications and CMS Web Interface Measure Specifications collection types:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C >=190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes **Updated denominator:** **For the eCQMs Specifications collection type: Revised:** Equals Initial Population **For the CMS Web Interface Measure Specifications collection types: Revised:** Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of ASCVD, including an ASCVD procedure, Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had laboratory result of LDL-C >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes

Category	Description
	The measure rate aggregation is revised to read: For the eCQM Specifications collection type: This measure is intended to have one reporting rate, which aggregates the following populations into a single performance rate for reporting purposes: Population 1: All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure, before the end of the measurement period. Population 2: Patients aged >= 20 years at the beginning of the measurement period who have ever had a laboratory test result of LDL-C >= 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. Population 3: Patients aged 40 to 75 years at the beginning of the measurement period with an active diagnosis of Type 1 or Type 2 diabetes at any time during the measurement period. For the purposes of this measure, a single performance rate can be calculated as follows: Performance Rate = (Numerator 1 + Numerator 2 +Numerator 3)/ [(Denominator 1 - Denominator Exclusions 1- Denominator Exceptions 1) + (Denominator 2 - Denominator Exclusions 2 - Denominator Exceptions 2) +(Denominator 3 - Denominator Exclusions 3 - Denominator Exceptions 3)] **Updated definition: For the MIPS CQMs Specifications collection type:** **Revised:** Lipoprotein Density Cholesterol (LDL-C) result – A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available, the direct LDL-C test result should be used. **Added:** - Statin-Associated Muscle Symptoms (SAMS) – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. The following ICD-10-CM codes are included in the Denominator Exception (G9781) to define SAMS: G72.0, G72.9, M60.9, M79.10. - Zypitamag and Nikita to statin medication therapy list. **Revised:** Caduet and Vytorin to 'Fixed Dose Combination'. **For the CMS Web Interface Measure Specifications collection type:** **Revised:** Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage): [Generic name] (Brand or trade name) and (-) Medication type, if applicable: [Atorvastatin] (Lipitor) - Statin [Fluvastatin] (Lescol XL or Lescol) - Statin [Lovastatin (Mevinolin)](Mevacor or Altoprev) -Statin [Pitavastatin] (Livalo or Zypitamag or Nikita) - Statin [Pravastatin Sodium] (Pravachol) - Statin [Rosuvastatin Calcium] (Crestor) - Statin [Simvastatin] (Zocor) - Statin [Amlodipine Besylate/Atorvastatin Calcium] (Caduet) – Fixed Dose Combination [Ezetimibe/Simvastatin] (Vytorin) – Fixed Dose Combination Statin-Associated Muscle Symptoms (SAMS) – The 2018 ACC/AHA/MS Guideline (Grundy et al., 2019) includes the following SAMS: myalgias, myositis, myopathy, or statin-associated autoimmune myopathy. Patients who experience significant or repeated statin-associated muscle symptoms may prefer not to take or continue statin therapy and therefore may be removed from the denominator. Lipoprotein Density Cholesterol (LDL-C) result - A fasting or non-fasting LDL-C laboratory test performed and direct or calculated test result documented in the medical record. When both direct and calculated test results are available on the same day, the direct LDL-C test result should be used. **Updated denominator: For the MIPS CQMs Specifications collection type: Revised:** Submission Criteria: 1) All patients who were previously diagnosed with or currently have an active diagnosis of clinical ASCVD, including an ASCVD procedure. 2) Patients aged ≥ 20 years at the beginning of the measurement period who have ever had a laboratory result of LDL-C ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia. 3) Patients aged 40 to 75 years at the beginning of the measurement period with Type 1 or Type 2 diabetes. **Updated denominator criteria is revised to read: For the MIPS CQMs Specifications collection type:** **Updated:** Submission Criteria 1: **Revised:** - All patients, regardless of age - Previously diagnosed or have an active diagnosis of clinical ASCVD, including ASCVD procedure. Submissiont Criteria 2: **Revised:** - Patient aged ≥ 20 years at the beginning of the measurement period - Any LDL-C laboratory test result ≥ 190 mg/dL - History of or active diagnosis of familial hypercholesterolemia Submission Criteria 3: **Removed:**

Category	Description
	Patient's highest fasting or direct LDL-C laboratory test result in the measurement period or two years prior to the beginning of the measurement period is 70 –189 mg/dL **Updated numerator guidance: For the CMS Web Interface Measure Specifications collection type: Revised:** These drugs may be used as a Denominator Exception if present in the patient's record accompanied by an appropriate conditional reason why the patient isn't taking the drug (e.g. statin-associated muscle symptoms or an allergy to statin medication) - Documentation of statin therapy prescribed or being taken during the measurement period can be completed during a telehealth encounter.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure to align with 2018 American College of Cardiology (ACC)/American Heart Association (AHA) cholesterol guidelines and recommendations. These revisions are reflected in multiple components of the measure specifications for all collection types. The measure definitions and/or guidance sections for all collection types were revised to align with and add clarity to the revisions within the measure to align with current clinical guidelines and recommendations. We propose to remove the denominator exception found in submission criteria 3 for patients with diabetes not taking statin therapy who have the most recent fasting or direct LDL-C laboratory test result < 70 mg/dL as it is no longer applicable as the denominator criteria was revised to remove LDL-C laboratory testing criteria. Additionally, we propse to add statin-associate muscle symptoms to the denominator exception for documentation of medical reason(s) for all submission criteria and all collection types as it would not be appropriate to prescribe statin therapy for this patient population. We proposed to update the numerator guidance for the CMS Web Interface Measure Specifications collection type to allow for the documentation of statin therapies prescribed or taken during the measurement period to be completed during a telehealth encounter as this aligns with the intent of the measure and clinical workflow. We propose to revise the statin medication therapy list for all collection types to reflect current clinical guidelines and recommendations. Additionally, we propose to update the denominator exclusions for all submission criterias and collection types to include a timing component in order to clarify when it must occur and for consistency in implementation.

D.71 Appropriate Workup Prior to Endometrial Ablation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	448
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.
Substantive Change:	**The measure denominator definition is revised to read:** Index Date –Date of first endometrial ablation during the performance period. **Updated denominator exclusion: Revised:** Patients who had an endometrial ablation procedure during the 12 months prior to the index date (exclusive of the index date). **The measure numerator is revised to read:** Patients who received endometrial sampling or hysteroscopy with biopsy and results were documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation. **The measure numerator options are revised to read:** **Performance Met:** Endometrial sampling or hysteroscopy with biopsy and results documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation **Performance Not Met:** Endometrial sampling or hysteroscopy with biopsy and results not documented during the 12 months prior to the index date (exclusive of the index date) of the endometrial ablation
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the measure denominator definition to reference the first endometrial ablation as the index date. This change aligns with the measure intent as the timing of the quality action should be assessed based on the date of the endometrial ablation procedure. We propose to revise the denominator exclusion for clarity in timing of previous endometrial ablations that may suffice for this exclusion. Additionally, we propose to revise the numerator and numerator options for clarity in timing of the quality action as well as to align with the revised definition for Index Date to ensure alignment with measure intent.

D.72 Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer

Category	Description
NQF # / eCQM NQF #:	1858 / N/A
Quality#:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.
Substantive Change:	**Updated denominator criteria: Added:** exclusion for telehealth
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add an exclusion for telehealth as adjuvant therapy would require an in-person encounter and this will ensure only the appropriate patients are being pulled into the denominator eligible patient population.

D.73 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient at three months (6 - 20 weeks) after the date of procedure. Assessment scores obtained via a telephone screening or prior to six weeks and after 20 weeks postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the six to 20 weeks following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.

D.74 Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained via a telephone screening or prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.

D.75 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months pre-operatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient three months (6 to 20 weeks) after the date of the procedure. Assessment scores obtained via a telephone screening or prior to 6 weeks and after 20 weeks postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the six to 20 weeks following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.

D.76 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v5
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**Updated logic definitions:** **Revised:** First Androgen Deprivation Therapy' to 'Androgen Deprivation Therapy Start Date'. **Added:** 'Androgen Deprivation Therapy for Urology Care Medication Active Start Dates' and 'Androgen Deprivation Therapy for Urology Care Medication Order Start Dates.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the logic to include order for androgen deprivation therapy as an option to meet eligibility for the initial patient population as these patients would be appropriate for inclusion to be assessed for the quality action.

D.77 Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	463
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Substantive Change:	**Updated numerator definition: Added:** Propofol for induction and maintenance of anesthesia.
Steward:	American Society of Anesthesiologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the numerator definition to add Propofol as this is a commonly used prophylactic antiemetic and aligns with current clinical recommendations.

D.78 Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively.
Substantive Change:	**The measure description is revised to read:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively **Updated instructions: Revised: NOTE**: This measure is a target-based measure with two ways to meet the numerator; either a postoperative ODI score that is less than or equal to 22 OR an improvement of 30 points or greater from the preoperative to postoperative score. It is expressed as a proportion or rate. Patients having received a lumbar fusion procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures for performance calculation. **The measure numerator is revised to read:** All eligible patients whose functional status is less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI Version 2.1a) patient reported outcome tool at one year (9 to 15 months) postoperatively **Updated numerator definition: Revised:** Preoperative Assessment Oswestry Disability Index (ODI version 2.1a)- A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative ODI was obtained, use the ODI that is the most recent and prior to the procedure. Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A postoperative ODI functional assessment score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained prior to nine months and after fifteen months postoperatively will not be used for measure calculation. If more than one postoperative ODI was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at one year (9 to 15 months) after the procedure AND the improvement is greater than or equal to 30 points. **The measure numerator note is revised to read:** NUMERATOR NOTE: It is recommended that both a preoperative and postoperative tool be administered to the patient to increase the chance that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1043 or G2143 is submitted. • ODI is not administered postoperatively at one year (9 to 15 months) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 9 months or greater than 15 months (1 year window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure improvement • Postoperative ODI was greater than 22 and preoperative ODI (to measure improvement) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure.) **The measure numerator options are revised to read:** **Performance Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of 30 points or greater. **Performance Not Met:** Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively. **Performance Not Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at one year (9 to 15 months) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within three months preoperatively AND at one year (9 to 15 months) postoperatively demonstrated an improvement of less than 30 points.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered. Additionally, we propose to update multiple components of the measure specifications to remove 'a change' and replace it with 'an improvement' as the intent of the measure is to assess if there was improvement in a patient's functional status.

D.79 Functional Status After Primary Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Measure Assessment Period (Performance Period) - The period of time following the procedure date that is in which a postoperative Oxford Knee Score (OKS) or KOOS, JR. functional status score can be obtained reflecting a one year post operative assessment with a 9 to 15 month window. If more than one postoperative assessment was obtained during the 9 to 15 month window, use the most recent score during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.

D.80 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**The measure description is revised to read:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively **The measure numerator is revised to read:** All eligible patients whose functional status is less than or equal to 22 OR an improvement of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) at three months (6 to 20 weeks) postoperatively **Updated numerator definition: Revised:** Preoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A preoperative ODI functional assessment score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained more than three months before the procedure will not be used for measure calculation. If more than one preoperative ODI was obtained, use the ODI that is the most recent and prior to the procedure. Postoperative Assessment Oswestry Disability Index (ODI version 2.1a) - A postoperative ODI functional assessment score can be obtained from the patient three months (6 to 20 weeks) after the date of procedure. Assessment scores obtained prior to six weeks and after twenty weeks postoperatively will not be used for measure calculation. If more than one postoperative ODI was obtained during the 6 to 20 weeks following the procedure, use the most recent score obtained during the allowable timeframe. ODI can be obtained below or at the following link https://eprovide.mapi-trust.org/instruments/oswestry-disability-index. Functional Status Target #2 - A patient who does not meet Functional Status Target #1 is assessed both preoperatively within 3 months prior to the procedure AND postoperatively at three months (6 to 20 weeks) after the procedure AND the improvement is greater than or equal to 30 points. **Updated instructions: Revised:** NOTE: This measure is a target-based measure with two ways to meet the numerator; either a postoperative ODI score that is less than or equal to 22 OR an improvement of 30 points or greater from the preoperative to postoperative score. It is expressed as a proportion or rate. Patients having received a lumbar discectomy/laminectomy procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures to be utilized for performance calculation. **The measure numerator note is revised to read:** NUMERATOR NOTE: It is recommended that both a preoperative and postoperative be administered to the patient increasing chances that one of the numerator targets will be met. The following situations are those in which the numerator target cannot be reached and Performance Not Met M1049 or G2145 is submitted. • ODI is not administered postoperatively at three months (6 to 20 weeks) • Functional status is measured using a different patient reported functional status tool or ODI version • Postoperative ODI is administered less than 6 weeks or greater than 20 weeks (3 month window) • Postoperative ODI is greater than 22 and no valid preoperative ODI to measure improvement • Postoperative ODI is greater than 22 and preoperative ODI (to measure improvement) is administered beyond the three month timeframe prior to and including the date of procedure (e.g. 6 months before procedure) **The measure numerator options are revised to read:** **Performance Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at three months (6 – 20 weeks) postoperatively was less than or equal to 22 OR Functional status measured by the ODI version 2.1a within three months preoperatively AND at three months (6 - 20 weeks) postoperatively demonstrated an improvement of 30 points or greater. **Performance Not Met:** Functional status was not measured by the Oswestry Disability Index (ODI version 2.1a) at three months (6 - 20 weeks) postoperatively. **Performance Not Met:** Functional status measured by the Oswestry Disability Index (ODI version 2.1a) at three months (6 – 20 weeks) postoperatively was greater than 22 AND Functional status measured by the ODI version 2.1a within three months preoperatively AND at three months (6 - 20 weeks) postoperatively demonstrated an improvement of less than 30 points.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered. Additionally, we propose to update multiple components of the measure specifications to remove 'a change' and replace it with 'an improvement' as the intent of the measure is to assess if there was improvement in a patient's functional status.

D.81 Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

Category	Description
NQF # / eCQM NQF #:	N/A / 3475e
Quality#:	472
CMS eCQM ID:	CMS249v4
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.
Substantive Change:	**Updated denominator exclusion: Revised:** The following risk factors may occur at any time in the patient's history or during the measurement period: Rheumatoid arthritis Hyperthyroidism Malabsorption Syndromes: celiac disease, inflammatory bowel disease, ulcerative colitis, Crohn's disease, cystic fibrosis, malabsorption Chronic liver disease Chronic malnutrition Osteoporotic fracture The following risk factors may occur any time in the patient's history prior to the start of the measurement period but do not need to be active at the start of the measurement period: Documentation of history of hip fracture in parent Glucocorticoids [cumulative medication duration >= 90 days]
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exclusion to remove the dosage requirements associate with glucocorticoid usage calculation to more accurately capture patients with relevant exposure and to exclude patients who had an osteoporotic fracture at any point in time, based upon stakeholder feedback. This will ensure that only patients appropriate for the assessment of the quality action are being included within the initial patient population.

D.82 Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated numerator definition: Revised:** Preoperative Assessment VAS Pain - A preoperative VAS pain scale score can be obtained from the patient any time up to three months preoperatively, inclusive of the date of the procedure. Assessment scores obtained via a telephone screening or more than three months before the procedure will not be used for measure calculation. If more than one preoperative VAS was obtained, use the VAS that is the most recent and prior to the procedure. Postoperative Assessment VAS Pain - A postoperative VAS pain scale score can be obtained from the patient one year (9 to 15 months) after the date of procedure. Assessment scores obtained via a telephone screening or prior to 9 months and after 15 months postoperatively will not be used for measure calculation. If more than one postoperative VAS was obtained during the 9 to 15 months following the procedure, use the most recent score obtained during the allowable timeframe.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the numerator definition to clarify which assessment should be utilized if multiple assessments are administered.

D.83 Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v3
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**Updated logic definitions: Revised:** the denominator exclusion "Patients with an initial BPH diagnosis that starts during, or within 30 days of hospitalization" logic has been updated to identify the encounter for the first diagnosis. **Updated value set/coding: Updated:** the denominator exclusion "Patients with a diagnosis of morbid obesity, or with a BMI Exam >40 before the follow up urinary symptom score" value set was updated to allow only calculated BMIs
Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to revise the logic of the denominator exclusion to ensure that the first encounter is being utilized to correctly identify the initial Benign Prostatic Hyperplasia (BPH) diagnosis to align with the intended timing component of the exclusion. Additionally, we propose to update the body mass index (BMI) denominator exclusion value set to allow for calculated BMIs to align with the measure intent and ensure only applicable patients are being excluded.

D.84 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).
Substantive Change:	**The measure description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil)
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We propose to update the measure description to align language across Focus on Therapeutic Outcomes, Inc. (FOTO) measures.

Table A: Proposed New Improvement Activities for the MIPS CY 2022 Performance Period/2024 MIPS Payment Year and Future Years

New Improvement Activity	
Proposed Activity ID:	**IA_AHE_XX**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Create and Implement an Anti-Racism Plan
Proposed Activity Description:	Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools.[1] The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The clinician or practice can also consider including in their plan ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.
Proposed Weighting:	High
Rationale:	This proposed activity aims to address systemic inequities, including systemic racism, as called for in Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, published January 20, 2021.[2] This activity begins with the premise that it is important to acknowledge systemic racism as a root cause for differences in health outcomes between socially-defined racial groups.[3, 4] We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, per the improvement activity definition at § 414.1305, because it supports clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care. This activity is intended to help clinicians move beyond analyzing data to taking real steps to naming and eliminating the causes of the disparities identified. We also propose making this activity high-weighted because clinicians will need considerable time and resources to develop a thorough anti-racism plan that is informed by data, and to implement it throughout the practice or system. See the definition for high weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_AHE_XX**
Proposed Subcategory:	Achieving Health Equity
Proposed Activity Title:	Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols

Appendix 2: Improvement Activities

Note: In this proposed rule, for the 2022 MIPS performance/2024 MIPS payment year and future years, we are proposing to add 7 new improvement activities, modify 15 previously adopted improvement activities, and remove 6 previously adopted improvement activities. These proposals are discussed in detail below. We request comments on our proposals.

Proposed Activity Description:	Create or improve, and then implement, protocols for identifying and providing appropriate support to: a) patients with or at risk for food insecurity, and b) patients with or at risk for poor nutritional status. (Poor nutritional status is sometimes referred to as clinical malnutrition or undernutrition and applies to people who are overweight and underweight.) Actions to implement this improvement activity may include, but are not limited to, the following: • Use Malnutrition Quality Improvement Initiative (MQii) or other quality improvement resources and standardized screening tools to assess and improve current food insecurity and nutritional screening and care practices. • Update and use clinical decision support tools within the clinician's electronic medical record to align with the new food insecurity and nutrition risk protocols. • Update and apply requirements for staff training on food security and nutrition. • Update and provide resources and referral lists, and/or engage with community partners to facilitate referrals for patients who are identified as at risk for food insecurity or poor nutritional status during screening. Activities must be focused on patients at greatest risk for food insecurity and/or malnutrition—for example patients with low income who live in areas with limited access to affordable fresh food, or who are isolated or have limited mobility.
Proposed Weighting:	Medium
Rationale:	Food insecurity is a widespread and worsening issue in the United States. Estimates indicate that the number of food insecure people in the United States increased from 35.2 million people (1 in 9 people) in 2019 to 45 million people (1 in 7 people) in 2020.[5] Older adults are particularly at risk because of low income, mobility issues, dementia, and other factors such as social isolation. Food insecurity also disproportionately affects Black and Latinx households.[6] Malnutrition is also widespread in the United States.[7] Both food insecurity and malnutrition are associated with worse health outcomes and higher spending on healthcare.[Error! Bookmark not defined.] For example, adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgical, and recovery outcomes.[8] The improvement activity fills a gap in the inventory, which does not currently include an improvement activity related to food insecurity or malnutrition. We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because ameliorating food insecurity and malnutrition leads to better health outcomes.[9,10] This activity creates an opportunity for clinicians to help address food insecurity and malnutrition, and provides the Malnutrition Quality Improvement Initiative as a resource.[11] Evidence indicates that they can help patients by increasing enrollment in the Supplemental Nutrition Assistance Program (SNAP) (https://www.fns.usda.gov/snap/supplemental-nutrition-assistance-program), which is associated with reduced food insecurity[12] or connecting their patients to other community resources. This activity also creates an opportunity for clinicians to help address malnutrition by ensuring patients in need receive a detailed nutritional assessment and appropriate nutritional care. We propose weighting this activity medium, because this activity may be accomplished by providing literature and/or facilitating a conversation with a patient during a regular visit. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health

Proposed Activity Title:	Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
Proposed Activity Description:	Create and implement a plan for trauma-informed care (TIC) that recognizes the potential impact of trauma experiences on patients and takes steps to mitigate the effects of adverse events in order to avoid re-traumatizing or triggering past trauma. Actions in this plan may include, but are not limited to, the following: • Incorporate trauma-informed training into new employee orientation • Offer annual refreshers and/or trainings for all staff • Recommend and supply TIC materials to third party partners, including care management companies and billing services • Identify patients using a screening methodology • Flag charts for patients with one or more adverse events that might have caused trauma • Use ICD-10 diagnosis codes for adverse events when appropriate TIC is a strengths-based healthcare delivery approach that emphasizes physical, psychological, and emotional safety for both trauma survivors and their providers.[13] Core components of a TIC approach are: awareness of the prevalence of trauma; understanding of the impact of past trauma on services utilization and engagement; and a commitment and plan to incorporate that understanding into training, policy, procedure, and practice.[14]
Proposed Weighting:	Medium
Rationale:	We propose this activity because the psychological impact of trauma influences the clinical care needs of a large population in the United States and adopting a TIC approach can help all clinicians avoid retraumatizing affected patients and support providers and staff who have experienced trauma themselves.[15] Research indicates that clinicians have a positive view of TIC but need more resources and support to apply the concepts to practice.[16] For the purposes of this proposed improvement activity, trauma is the experience of a harmful or life-threatening event or series of events and their longer-term psychological impact, which can include development of post-traumatic stress disorder (PTSD) and changes to brain functioning and even genetics.[17] Approximately 60 percent of men and 50 percent of women in the U.S. have experienced trauma in their lifetimes and 7-8 percent of the population will have PTSD at some point in their lives.[18] Multi-generational trauma, whereby experiences that traumatized earlier generations, such as the genocide of Native American tribes, are passed down, impact many families and communities.[19] Clinicians (and not just mental health clinicians) who take a TIC approach anticipate and avoid institutional processes and individual practices that are likely to retraumatize individuals who have histories of trauma.[20] We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because trauma-informed approaches in healthcare are associated with improved outcomes for patients.[21] We propose weighting this activity medium, because this activity may be accomplished by conducting a training, providing resources, or incorporating new procedures into a clinician's practice. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_BMH_XX**
Proposed Subcategory:	Behavioral and Mental Health
Proposed Activity Title:	Promoting Clinician Well-Being
Proposed Activity Description:	Develop and implement programs to support clinician well-being and resilience—for example, through relationship-building opportunities, leadership development plans, or

	creation of a team within a practice to address clinician well-being—using one of the following approaches: • Completion of clinician survey on clinician well-being with subsequent implementation of an improvement plan based on the results of the survey. • Completion of training regarding clinician well-being with subsequent implementation of a plan for improvement.
Proposed Weighting:	High
Rationale:	We believe this activity will help clinicians prioritize and improve their own well-being and the well-being of their staff and colleagues. Focusing on improving clinician well-being is especially critical now, given the stress that the COVID-19 public health emergency has exerted on clinicians. Many organizations, including the National Academies of Sciences, Engineering, and Medicine,[22] have prioritized interventions to improve clinician well-being. Studies indicate that clinician burnout, including emotional exhaustion, depersonalization, and reduced personal accomplishment, is associated with poorer quality healthcare and reduced safety for patients.[23, 24] Studies also indicate that some interventions have been shown to reduce burnout and improve well-being.[25] This improvement activity fills a gap because the inventory does not currently include an improvement activity related to clinician well-being. We believe this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because promoting clinician well-being and mitigating burnout leads to better quality health care and increased patient safety.[25] Given the impact of the COVID-19 pandemic on the medical community and the considerable time and resources required to mitigate its effects and promote well-being among clinicians, we believe that this activity should be weighted as high, in alignment with our definition in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_ERP_XX**
Proposed Subcategory:	Emergency Response and Preparedness
Proposed Activity Title:	Implementation of a Personal Protective Equipment (PPE) Plan
Proposed Activity Description:	Implement a plan to acquire, store, maintain, and replenish supplies of personal protective equipment (PPE) for all clinicians or other staff who are in physical proximity to patients. In accordance with guidance from the Centers for Disease Control and Prevention (CDC) the PPE plan should address: • Conventional capacity: PPE controls that should be implemented in general infection prevention and control plans in healthcare settings, including training in proper PPE use. • Contingency capacity: actions that may be used temporarily during periods of expected PPE shortages. • Crisis capacity: strategies that may need to be considered during periods of known PPE shortages. The PPE plan should address all of the following types of PPE: • Standard precautions (e.g., hand hygiene, prevention of needle-stick or sharps injuries, safe waste management, cleaning and disinfection of the environment) • Eye protection • Gowns (including coveralls or aprons) • Gloves • Facemasks • Respirators (including N95 respirators)
Proposed Weighting:	Medium
Rationale:	The COVID-19 pandemic illustrated the importance of maintaining adequate PPE supplies for caregivers. Especially early in the pandemic, inadequate PPE supplies reduced access to care and exposed healthcare workers to unnecessary risk.[26]

	While clinicians may be following surge capacity procedures, they may not have a written plan for both preventing and preparing for surge capacity. In a survey conducted in mid-March of 2020, over 50 percent of physician practices cited a lack of supplies as an obstacle to caregiving.[27] Also, in a 2009 survey of American College of Emergency Physician Disaster Medicine Section members, fewer than 75 percent of respondents indicated that their emergency department had a plan for responding to pandemic influenza and other infectious disease threats.[28] This proposed improvement activity is based on the CDC guidelines for optimizing PPE supplies [29] and aligns with World Health Organization guidelines.[30] We believe that including this improvement activity in the inventory would encourage formalizing the process for creating a PPE plan, training staff, and ensuring adequate PPE inventory. Thus, it has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because both clinicians and their patients will be safer when responding to epidemics, reducing the transmission of viruses and allowing clinicians to provide patients with appropriate care because supplies are available. We propose that this activity should be weighted as medium, because it may be accomplished by conducting a training, providing resources, or incorporating new procedures into a clinician's practice. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	**IA_ERP_XX**
Proposed Subcategory:	Emergency Response and Preparedness
Proposed Activity Title:	Implementation of a Laboratory Preparedness Plan
Proposed Activity Description:	Develop, implement, update, and maintain a preparedness plan for a laboratory intended to support continued or expanded patient care during COVID-19 or another public health emergency. The plan should address how the laboratory would maintain or expand patient access to health care services to improve beneficiary health outcomes and reduce healthcare disparities. For laboratories without a preparedness plan, clinicians would meet with stakeholders, record minutes, and document a preparedness plan, as needed. The laboratory must then implement the steps identified in the plan and maintain them. For laboratories with existing preparedness plans, clinicians should review, revise, or update the plan as necessary to meet the needs of the current PHE, implement new procedures, and maintain the plan. Maintenance of the plan in this activity could include additional hazard assessments, drills, training, and/or developing checklists to facilitate execution of the plan. Participation in debriefings to evaluate the effectiveness of plans are additional examples of engagement in this activity.
Proposed Weighting:	Medium
Rationale:	The COVID-19 pandemic demonstrated a need for many laboratories to develop and implement protocols to respond to the public health emergencies, as an increase in demand (due to a surge in COVID testing) and reduced staffing (due to needing to maintain distancing and other factors, such as childcare becoming unavailable) compromised laboratory functioning.[31] We believe that including this improvement activity in the inventory would encourage formalizing, updating, and maintaining preparedness plans to better equip laboratories to address another public health emergency, as well as other disasters such as floods, fires, or other emergencies. Such a plan will allow laboratory staff to respond and

	maintain operations during emergency situations. Thus, it has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes, because if needed laboratory services increase with the surge in demand, staff will be prepared to meet those needs. We propose weighting this activity medium, because this activity may be accomplished by developing a plan and training staff on that plan. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).
New Improvement Activity	
Proposed Activity ID:	IA_PSPA_XX
Proposed Subcategory:	Patient Safety and Practice Assessment
Proposed Activity Title:	Application of CDC's Training for Healthcare Providers on Lyme Disease
Proposed Activity Description:	Apply the Centers for Disease Control and Prevention's (CDC) Training for Healthcare Providers on Lyme Disease using clinical decision support (CDS). CDS for Lyme disease should be built directly into the clinician workflow and support decision making for a specific patient at the point of care. Specific examples of how the guideline could be incorporated into a CDS workflow include but are not limited to: electronic health record (EHR) based prescribing prompts, order sets that require review of guidelines before prescriptions can be entered, and prompts requiring review of guidelines before a subsequent action can be taken in the record.
Proposed Weighting:	Medium
Rationale:	Lyme disease has a high burden of disease, with approximately 476,000 cases diagnosed and treated annually. Additionally, the places where Lyme disease is common is expanding.[32] We believe that including this improvement activity in the inventory would increase knowledge about Lyme disease. The CDC has developed a training course to support clinicians in identifying and treating Lyme disease, and this course would provide foundational knowledge to incorporate Lyme disease diagnosis and treatment into the workflow using CDS.[33] It has the potential to improve clinical practice and care delivery and is likely to result in improved outcomes; additional education to improve Lyme disease testing, ordering, and reporting systems are likely to improve patient care, reduce errors, and result in better Lyme disease-related outcomes. [34, 35, 36] We propose weighting this activity medium because this activity may be accomplished by conducting a training and incorporating new procedures into a clinician's practice. The estimated level of effort for clinicians is comparable to other medium-weighted activities in the inventory, and less than that of high-weighted activities. See the definition of medium weighting in the CY 2019 PFS final rule (83 FR 59780 through 59781).

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Table B: Proposed Changes to Previously Adopted Improvement Activities for the 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_AHE_1**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Engagement of new Medicaid patients and follow-up
Current Activity Description:	Seeing new and follow-up Medicaid patients in a timely manner, including individuals dually eligible for Medicaid and Medicare. A timely manner is defined as within 10 business days for this activity.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). The proposed modified activity would continue to address the important objective of providing timely care to Medicaid patients, but also expand the target population to include all patients who are underserved and may face barriers to timely access to appropriate care. We also propose modifying the description so that, instead of stating patients should receive follow-up in a "timely manner," defined as within 10 business days, clinicians would use their own time-to-treat data (i.e., data measuring the time between clinician identifying a need for an appointment and the patient having a scheduled appointment) to ensure that patients receive follow-up within standard guidelines and create, implement and monitor an approach for improvement in engagement in care. We want to broaden the description, because the amount of time that is clinically relevant for a follow up visit varies widely,[1] and therefore, setting a specific definition of "timely manner" may not be clinically appropriate for all patients. The proposed modification acknowledges this variation and encourages clinicians to use their own time-to-treat data and standard practice guidelines to enhance engagement. The proposed modified activity describes that this approach to improving engagement in care may include screening for treatment barriers, especially transportation barriers, and providing resources to patients who need assistance, including access to federally-mandated Medicaid transportation benefits. Lack of suitable transportation can pose a barrier to accessing needed care for many underserved patients—particularly for those who are elderly, disabled, or low-income.[2] As finalized in federal regulation (42 CFR 431.53 and 440.170), Medicaid beneficiaries are eligible for the non-emergency medical transportation benefit, which assures transportation to and from non-emergency medical care for those without other options.[3] This activity is intended to encourage clinicians to direct Medicaid beneficiaries and other underserved patients to access resources to reduce barriers to their timely access of needed care and ultimately help them achieve better health outcomes. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it creates more flexibility around the timeline for follow-up by using time-to-treat data, specifies that these data guide an approach for patient engagement, and addresses a broader range of underserved populations.
Proposed Revised Activity Title	Enhance Engagement of Medicaid and Other Underserved Populations
Proposed Revised Activity Description:	To improve responsiveness of care for Medicaid and other underserved patients: use time-to-treat data (i.e., data measuring the time between clinician identifying a need for an appointment and the patient having a scheduled appointment) to identify patterns by which care or engagement with Medicaid patients or other groups of underserved patients has not achieved standard practice guidelines; and with this information, create, implement, and monitor an approach for improvement. This approach may include screening for patient barriers to treatment, especially transportation barriers, and providing resources to improve engagement (e.g., state Medicaid non-emergency medical transportation benefit).
Current Improvement Activity	
Current Activity ID:	**IA_AHE_5**

Current Subcategory:	Achieving Health Equity
Current Activity Title:	MIPS Eligible Clinician Leadership in Clinical Trials or Community-Based Participatory Research (CBPR)
Current Activity Description:	MIPS eligible clinician leadership in clinical trials, research alliances or community-based participatory research (CBPR) that identify tools, research or processes that can focuses on minimizing disparities in healthcare access, care quality, affordability, or outcomes.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2018 Quality Payment Program final rule (82 FR 54175). This proposed modification would add as an explicit option that the research could focus on addressing health-related social needs as drivers of health. Risks for health-related social needs are more acute and widespread in underserved communities.[4] These risks are linked to worse health outcomes and addressing them can reduce costs.[5] The modification would also change verbiage in ways that clarify the activity, but do not affect the intent of the activity. The health-related social needs included in the proposed modification are aligned with our Accountable Health Communities (AHC) Model (https://innovation.cms.gov/innovation-models/ahcm), which looks at the impact of identifying and addressing patients' health-related social needs on their health outcomes. AHC has prioritized five areas of health-related social needs, namely: food insecurity, housing insecurity, transportation, utilities, and interpersonal safety.[6] These areas were selected as priority, because there is high-quality evidence linking it with poor health or increased health care utilization and cost, there are community providers who can help meet the need, and health care providers are not yet comprehensively screening for or addressing these needs.[7] We propose to modify this improvement activity to identify the same five health-related social needs prioritized in the AHC Model as potential areas of research. Criteria for selecting new improvement activities, which we are proposing to update in section IV.A.3.d.(3)(c)(i), align with those used for prioritizing health-related social needs. With this modification, this improvement activity would become more explicitly a part of our plan to help clinicians provide patient-centered care to patients who have complex and multi-faceted needs. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it explicitly includes research into health-related social needs, which are central to understanding and addressing disparities in achieving positive health outcomes . We believe that we will achieve the objectives of the Quality Payment Program—specifically, to improve beneficiary population health, to improve the care received by Medicare beneficiaries, and to lower costs to the Medicare program—by helping address health-related social needs.
Proposed Revised Activity Description:	Lead clinical trials, research alliances, or community-based participatory research (CBPR) that identify tools, research, or processes that focus on minimizing disparities in healthcare access, care quality, affordability, or outcomes. Research could include addressing health-related social needs like food insecurity, housing insecurity, transportation barriers, utility needs, and interpersonal safety.
Current Improvement Activity	
Current Activity ID:	**IA_BE_1**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of certified EHR to capture patient reported outcomes
Current Activity Description:	In support of improving patient access, performing additional activities that enable capture of patient reported outcomes (e.g., home blood pressure, blood glucose logs, food diaries, at-risk health factors such as tobacco or alcohol use, etc.) or patient activation measures through use of certified EHR technology, containing this data in a separate queue for clinician recognition and review.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to modify the activity by replacing examples of patient reported outcomes with current industry standards -- functional status, symptoms and symptom burden, health behaviors, and patient experience.

	We also propose to include a definition for patient activation[8] -- measures of patient involvement in their care -- to improve clarity of the activity. Finally, we also propose to simplify the wording in ways that clarify the activity but do not affect the purpose. These proposed modifications would improve the accuracy, applicability, and clarity of the activity. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it promotes clarity by providing more accurate and current industry standard patient reported outcomes.
Proposed Revised Activity Description:	To improve patient access, perform activities beyond routine care that enable capture of patient reported outcomes (e.g., related to functional status, symptoms and symptom burden, health behaviors, or patient experience) or patient activation measures (i.e., measures of patient involvement in their care) through use of certified electronic health record technology, and record these outcomes data for clinician review.
Current Improvement Activity	
Current Activity ID:	**IA_BE_6**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Collection of and follow-up on patient experience and satisfaction data on beneficiary engagement
Current Activity Description:	Collection of and follow-up on patient experience and satisfaction data on beneficiary engagement, including development of improvement plan.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We are proposing to combine multiple activities into this IA-BE-6 improvement activity to remove overlapping content and improve the applicability and ease of use. In addition to this activity, the previously adopted BE_13 (81 FR 77825) and PSPA_11 (81 FR 77825) improvement activities also require the collection of patient experience and satisfaction data with the objective of increasing patient-centeredness of care. The previously adopted activity descriptions are as follows: • IA_BE_13: Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms. • IA_PSPA_11: Participation in the Consumer Assessment of Healthcare Providers and Systems Survey (CAHPS) or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets) We propose to modify IA_BE_6 to include additional detail covering the unique content of IA_BE_13 and IA_PSPA_11. Specifically, we propose to add surveys such as CAHPS, advisory councils, and other mechanisms in the modified version of BE_6 as options for tools used for collecting the patient experience data. We also propose to update the title of the improvement activity to better reflect the full scope of the revised activity description. We also propose to add language that would encourage clinicians to consider the linguistic needs of their population, so that the satisfaction survey results can include the perspectives of patient groups who may not feel comfortable taking a survey in English.
Proposed Revised Title:	Regularly Assess Patient Experience of Care and Follow Up on Findings
Proposed Revised Activity Description:	Collect and follow up on patient experience and satisfaction data. This activity also requires follow-up on findings of assessments, including the development and implementation of improvement plans. To fulfill the requirements of this activity, eligible clinicians can use surveys (e.g., Consumer Assessment of Healthcare Providers and Systems Survey), advisory councils, or other mechanisms. Clinicians may consider implementing patient surveys in multiple languages, based on the needs of their patient population.

Current Improvement Activity	
Current Activity ID:	**IA_BE_16**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Evidenced-based techniques to promote self-management into usual care
Current Activity Description:	Incorporate evidence-based techniques to promote self-management into usual care, using techniques such as goal setting with structured follow-up, Teach Back, action planning or motivational interviewing.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to combine this IA_BE_16 with the previously adopted IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 because of overlapping and duplicative content and to improve the applicability and ease of use of the inventory. The above previously adopted improvement activities included effective interventions for helping patients better engage in self-management. The previously adopted activity descriptions are as follows: • IA_BE_17: Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or "How's My Health"). (81 FR 77825) • IA_BE_18: Provide peer-led support for self-management. (81 FR 77825) • IA_BE_20: Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community. (81 FR 77825) • IA_BE_21: Provide self-management materials at an appropriate literacy level and in an appropriate language. (81 FR 77825) We are proposing to change IA_BE_16 to include additional detail covering the unique content of IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21. Specifically, we are proposing to add tools for self-management, peer-led support, provision of self-management materials, and retain the examples of evidence-based approaches patients better engage in self-management included in the original IA_BE_16: goal setting with structured follow-up,[9] Teach-back methods,[10] action planning,[11] assessment of need for self-management (e.g., the Patient Activation Measure[12]), and motivational interviewing[13] as options for tools and resources to provide patients as part of fulfilling the requirements for the activity. These tools and techniques could be particularly helpful for people with substance use disorders and individuals managing chronic physical conditions such as diabetes and heart disease[14]. We also propose to add that evidence-based techniques for promoting self-management should be culturally and linguistically tailored.
Proposed Revised Activity Title:	Promote Self-management in Usual Care
Proposed Revised Activity Description:	To help patients self-manage their care, incorporate culturally and linguistically tailored evidence-based techniques for promoting self-management into usual care, and provide patients with tools and resources for self-management. Examples of evidence-based techniques to use in usual care include: goal setting with structured follow-up, Teach-back methods, action planning, assessment of need for self-management (e.g., the Patient Activation Measure), and motivational interviewing. Examples of tools and resources to provide patients directly or through community organizations include: peer-led support for self-management, condition-specific chronic disease or substance use disorder self-management programs, and self-management materials.
Current Improvement Activity	
Current Activity ID:	**IA_BE_25**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Drug Cost Transparency
Current Activity Description:	To receive credit for this improvement activity, MIPS eligible clinicians must attest that their practice provides counseling to patients and/or their caregivers about the costs of drugs and the patients' out-of-pocket costs for the drugs. If appropriate, the clinician must also explore with their patients the availability of alternative drugs and patients' eligibility for patient assistance programs that provide free medications to people who cannot afford to buy their medicine. One source of information for pricing of

	pharmaceuticals could be a real-time benefit tool (RTBT), which provides to the prescriber, real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. (CMS finalized in the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses final rule (84 FR 23832, 23883) that beginning January 1, 2021 Medicare Part D plans will be required to implement one or more RTBT(s).)
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2020 PFS final rule (84 FR 63539). In the CY 2020 PFS final rule (84 FR 63515), we adopted IA_BE_25, titled "Drug Cost Transparency to include requirements for use of real-time benefit tools" beginning with the 2020 performance year and for subsequent years. It allows a real-time benefit tool (RTBT) to be one source of information for pricing of pharmaceuticals, which provides to the prescriber real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary. The 2021 Consolidated Appropriations Act (H.R. 116-133, Pub. L. 116-260) subtitle B included section 119 "Increasing the use of real-time benefit tools to lower beneficiary costs" subsection (c) "Inclusion of Use of Real-Time Electronic Information in Shared Decision-Making Under MIPS" amended Section 1848(q)(2)(B)(iii)(IV) of the Act by adding at the end the following new sentences: ``This subcategory shall include as an activity, for performance periods beginning on or after January 1, 2022, use of a real-time benefit tool as described in section 1860D-4(o). The Secretary may establish this activity as a standalone or as a component of another activity." In response to this amendment, in this proposed rule, we propose to modify this improvement activity such that beginning with the 2022 MIPS performance period/2024 MIPS payment year and for subsequent years the activity would require use of RTBT in order to receive credit for this activity. As previously finalized, use of RTBT is optional. We also propose to update the description in ways that clarify the activity, but do not affect the intent of the activity. We believe that requiring RTBT would make this activity more likely to reduce the costs of care. As explained in the CY 2019 Modernizing Part D final rule (84 FR 23832), RTBTs that are integrated with at least one prescriber's e-prescribing and electronic medical record systems can make beneficiary-specific drug coverage and cost information visible to prescribers. Using RTBT thus allows the prescriber and patient, when appropriate, to choose among clinically acceptable alternatives while weighing costs. By making RTBT a requirement, this modification would also require prescribers to look for alternative drugs, in contrast to the existing activity where such comparisons are optional. We believe that furthering prescription price transparency is critical to lowering overall drug costs and patients' out-of-pocket costs and improving medication adherence. Additionally, it can help advance efforts to improve patient safety, quality of care, and efficiencies and cost savings in the delivery of care.
Proposed Revised Activity Description:	Provide counseling to patients and/or their caregivers regarding: costs of medications using a real time benefit tool (RTBT) which provides to the prescriber real-time patient-specific formulary and benefit information for drugs, including cost-sharing for a beneficiary
Current Improvement Activity	
Current Activity ID:	**IA_CC_14**
Current Subcategory:	Care Coordination
Current Activity Title:	Practice improvements that engage community resources to support patient health goals
Current Activity Description:	Develop pathways to neighborhood/community-based resources to support patient health goals that could include one or more of the following: • Maintain formal (referral) links to community-based chronic disease self-management support programs, exercise programs and other wellness resources with the potential for bidirectional flow of information; and provide a guide to available community resources. • Including through the use of tools that facilitate electronic communication

	between settings; • Screen patients for health-harming legal needs; • Screen and assess patients for social needs using tools that are preferably health IT enabled and that include to any extent standards-based, coded question/field for the capture of data as is feasible and available as part of such tool; and/or • Provide a guide to available community resources.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). The previously adopted improvement activity includes screening as one option to assess patients specifically for social and legal needs. We propose to modify this improvement activity to instead require screening for a range of health-related social needs using evidence-based tools before and in addition to supporting connections to community resources. We believe that screening patients using evidence-based tools can help clinicians adopt a more systematic approach to addressing health related social needs among their patient population, including effective documentation and follow-up, and avoid missing patients who have such needs. Including screening in addition to supporting connections to community resources, represents a continuum of support that clinicians can provide to patients from within the health system. We also propose to remove the promotion of systems for communication that have the "potential for bi-directional flow of information" and the option for using "tools that facilitate electronic communication between settings." In many communities, the resources and programs that might best provide patients who have health-related social needs with support may not have the baseline technological capacity to engage with clinician groups in ways that eclipse basic forms of communication like phone and email. We also propose to add an option for using electronic health records to document screening results, trigger follow-up, and analyze data to better tailor approaches. For practices that already have processes for enabling connections to community resources established, this option would allow continued improvement and provision of more streamlined and systematized support to patients in need. The specific set of health-related social needs that clinicians might choose to prioritize remains part of the improvement activity, as does examples that were previously mentioned in the activity—for example, health-related legal needs. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it requires clinicians to both screen for and address health related social needs, which are major contributors to health care access and health outcomes. In light of the above list of proposed changes in this modification, we are also proposing to increase the weight for this activity from medium to high. Specifically, the modifications now require screening in addition to an activity that links patients to community resources. Previously, the activity required screening *or* linkages to community. Conducting screening then devoting clinical staff time to using that data to identify and disseminate appropriate community resource information to patients takes considerable time and resources. We are proposing to increase the weight for this activity from medium to high to reflect the additional effort required, per high-weight criteria finalized in the CY 2019 PFS final rule (83 FR 59780 through 59781).
Proposed Weighting:	High
Proposed Revised Activity Description:	Select and screen for the health-related social needs (HRSN) that are relevant for your patient population using tools that have been tested with underserved populations. If possible, use a screening tool that is health IT-enabled and includes standards-based, coded question/field for the capture of data. After screening, address HRSNs identified through at least one of the following: • Update a guide to available community resources and provide it to patients who are found to be at risk in one or more HRSN area;

	• Maintain formal (referral) links to key community resources and programs to strengthen the referral process, implementing closed-loop referrals where feasible; or • Record findings of screening and trigger follow-up within the electronic health record (EHR); then analyze EHR data on patients with one or more HRSN needed to identify and implement approaches to better serve their holistic needs through linkages with community resources. HRSNs prioritized by your practice might include health-harming legal needs, which require both health and legal support to resolve, areas such as food and housing insecurity, or needs such as exercise, nutrition, or chronic disease self-management.
Current Improvement Activity	
Current Activity ID:	**IA_CC_15**
Current Subcategory:	Care Coordination
Current Activity Title:	PSH Care Coordination
Current Activity Description:	Participation in a Perioperative Surgical Home (PSH) that provides a patient-centered, physician-led, interdisciplinary, and team-based system of coordinated patient care, which coordinates care from pre-procedure assessment through the acute care episode, recovery, and post-acute care. This activity allows for reporting of strategies and processes related to care coordination of patients receiving surgical or procedural care within a PSH. The clinician must perform one or more of the following care coordination activities: • Coordinate with care managers/navigators in preoperative clinic to plan and implementation comprehensive post discharge plan of care; • Deploy perioperative clinic and care processes to reduce post-operative visits to emergency rooms; • Implement evidence-informed practices and standardize care across the entire spectrum of surgical patients; or • Implement processes to ensure effective communications and education of patients' post-discharge instructions.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2018 Quality Payment Program final rule (82 FR 54175). We are proposing to increase the weight for this activity from medium to high, because it came to our attention that the level of effort to complete this activity was better aligned to our high-weight criteria, which specifies that high-weight activities reflect high intensity activities, requiring significant investment of time and resources. This activity requires team-based, interdisciplinary care coordinated across multiple care settings and requires efforts to both plan for and implement the selected care coordination actions. We note that the activity description would remain the same.
Proposed Weighting:	High
Current Improvement Activity	
Current Activity ID:	**IA_EPA_1**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
Current Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent and emergent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a consistent MIPS eligible clinician, group or care team when needed for urgent care or transition management.

Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to remove references to a "consistent" MIPS eligible clinician, group or care team, because the requirement for a consistent clinician is unclear and unnecessary to achieve the activity's objectives. We also propose to limit the scope of the activity to "urgent care" only rather than both "urgent and emergent care," because emergent care would only require the activity's interventions when also urgent. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because the improved clarity will promote expanded access to MIPS eligible clinicians in urgent care settings. We believe that these modifications help clarify the nature and intent of this activity, and thus will help clinicians selecting it to improve access to care for their patients.
Proposed Revised Activity Description:	Provide 24/7 access to MIPS eligible clinicians, groups, or care teams for advice about urgent care (e.g., MIPS eligible clinician and care team access to medical record, cross-coverage with access to medical record, or protocol-driven nurse line with access to medical record) that could include one or more of the following: • Expanded hours in evenings and weekends with access to the patient medical record (e.g., coordinate with small practices to provide alternate hour office visits and urgent care); • Use of alternatives to increase access to care team by MIPS eligible clinicians and groups, such as e-visits, phone visits, group visits, home visits and alternate locations (e.g., senior centers and assisted living centers); and/or • Provision of same-day or next-day access to a MIPS eligible clinician, group or care team when needed for urgent care or transition management.
Current Improvement Activity	
Current Activity ID:	**IA_EPA_2**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Use of telehealth services that expand practice access
Current Activity Description:	Use of telehealth services and analysis of data for quality improvement, such as participation in remote specialty care consults or teleaudiology pilots that assess ability to still deliver quality care to patients.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 QPP final rule (81 FR 77825). We propose to shift the focus of the activity to developing standardized approaches for telehealth in their daily practice and away from the analysis of data to evaluate effectiveness. This proposed shift retains the objective of the original activity, namely, of improving health outcomes for patients utilizing telehealth services. We believe this proposed shift makes the activity more relevant, because while telehealth has become a routine part of health care during the COVID-19 pandemic and is perceived as effective by clinicians and patients, clinicians may not have implemented it in a standardized manner or as widely as possible due to the rapid adaptation needed during the pandemic.[15] We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it promotes creation and implementation of standardized telehealth services, which can improve access and quality of care by offering another mode by which patients can interact with their care team.
Proposed Revised Activity Description:	Create and implement a standardized process for providing telehealth services to expand access to care.
Current Improvement Activity	
Current Activity ID:	**IA_PM_6**
Current Subcategory:	Population Management
Current Activity Title:	Use of toolsets or other resources to close health care disparities across communities
Current Activity Description:	Take steps to improve healthcare disparities, such as Population Health Toolkit or other resources identified by CMS, the Learning and Action Network, Quality Innovation Network, or National Coordinating Center. Refer to the local Quality Improvement Organization (QIO) for additional steps to take for improving health status of communities as there are many steps to select from for satisfying this activity. QIOs

	work under the direction of CMS to assist eligible clinicians and groups with quality improvement, and review quality concerns for the protection of beneficiaries and the Medicare Trust Fund.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to add language that is more explicit about the improvement activity's focus on using population health data analysis to assess the prevalence of inequities in a practice and community. Specifically, we propose to modify the activity description to specify that population health data analysis tools should be used to identify health inequities; clinicians should then assess the options for effective interventions to address those inequities.[16] We also are proposing to add a requirement that clinicians create, refine, and implement an action plan to address inequities based on the data analysis conducted. We are also proposing to remove references to the Learning and Action Network, Quality Innovation Network, and National Coordinating Center as organizations that may identify tools or resources, because they may not be appropriate resources to support clinicians in assessing and addressing health disparities. Population health data analytic tools may be identified in a number of ways, and we seek to keep the activity broad in this manner. We also propose to replace the term "disparities" with "inequities" in both the title and description of the activity, which acknowledges structural problems like racism are inequities (i.e., state of being unfair) rather than using the term disparities, which is defined as being different or not at parity but does not clearly state the unjustness of the result. We are also proposing to modify the title to recognize that inequities in both health (i.e., status and outcomes) and health care (i.e., access, quality, and safety) may be addressed. With the proposed modifications, clinicians attesting to this improvement activity would need to first analyze inequities in their patient populations, and then use that data to identify and then address issues or gaps. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it is more focused on a data-driven approach to population health analysis and requires practices to use this data to inform a formal action planning process to address them.
Proposed Revised Activity Title:	Use of Toolsets or Other Resources to Close Health and Health Care Inequities Across Communities
Proposed Revised Activity Description:	Address inequities in health outcomes by using population health data analysis tools to identify health inequities in the community and practice, and assess options for effective and relevant interventions such as Population Health Toolkit or other resources identified by the clinician, practice, or by CMS. Based on this information, create, refine, and implement an action plan to address and close inequities in health outcomes and/or health care access, quality, and safety.
Current Improvement Activity	
Current Activity ID:	**IA_PM_11**
Current Subcategory:	Population Management
Current Activity Title:	Regular review practices in place on targeted patient population needs
Current Activity Description:	Implementation of regular reviews of targeted patient population needs, such as structured clinical case reviews, which includes access to reports that show unique characteristics of eligible clinician's patient population, identification of vulnerable patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to make explicit the acknowledgement that structural issues, like racism, are a root cause of many disparities in health outcomes across populations.

	Specifically, we propose to modify the improvement activity to encourage clinicians to explore structural issues like racism explicitly and openly during their reviews of targeted patient population needs. We propose to remove reference to "vulnerable patients" and replace it with "underserved patients" to better clarify that there is nothing inherently vulnerable about a person. Instead, their poorer health outcomes are due to systemic failures within and beyond the health system—failures which leave the health needs of underserved communities unmet. We believe these additions would allow clinicians to gain perspective and ideas beneficial to their patients by specifically identifying underserved patients, related structural inequities such as those due to racism, and tailor treatment needs and identify community resources to address those problems. We are also proposing to modify the description language in ways that clarify the activity, but do not change the intent. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it requires clinicians to implement regular reviews of patient population needs to identify and address the needs of underserved populations and connect those patients to resources in the community.
Proposed Revised Activity Description:	Implement regular reviews of targeted patient population needs, such as structured clinical case reviews, which include access to reports that show unique characteristics of eligible clinician's patient population, identification of underserved patients, and how clinical treatment needs are being tailored, if necessary, to address unique needs and what resources in the community have been identified as additional resources. The review should consider how structural inequities, such as racism, are influencing patterns of care and consider changes to acknowledge and address them. Reviews should stratify patient data by demographic characteristics and health related social needs to appropriately identify differences among unique populations and assess the drivers of gaps and disparities and identify interventions appropriate for the needs of the sub-populations.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_6**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Consultation of the Prescription Drug Monitoring program
Current Activity Description:	Clinicians would attest to reviewing the patients' history of controlled substance prescription using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. For the transition year, clinicians would attest to 60 percent review of applicable patient's history. For the Quality Payment Program Year 2 and future years, clinicians would attest to 75 percent review of applicable patient's history performance.
Current Weighting:	High
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to increase the percentage of applicable patients for whom clinicians must review prescription history within the PDMP from 75 percent to 100 percent and remove language referencing prior year requirements, which are now obsolete. States are increasingly mandating that providers review the PDMP for all applicable patients.[17] We also propose to include an exception for patients receiving palliative and hospice care, as they are exempt from CDC prescribing guidelines.[18] The CDC has identified increasing use of PDMP as the most promising state-level strategy for improving clinical care and outcomes for at-risk patients.[19] We support the continued efforts of clinicians to increase usage of PDMP in their practice. We also propose to modify the description language in ways that clarify the activity but do not affect its intent. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because it supports use of prescription drug monitoring programs to reduce overprescribing of controlled

	substance prescriptions lasting longer than three days,[20] which can lead to substance use disorder.
Proposed Revised Activity Description:	Review the history of controlled substance prescriptions for 100 percent* of patients using state prescription drug monitoring program (PDMP) data prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription lasting longer than 3 days. *Apply exceptions for patients receiving palliative and hospice care.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_18**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Measurement and improvement at the practice and panel level
Current Activity Description:	Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards, that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel); and/or • Use relevant data sources to create benchmarks and goals for performance at the practice level and panel level.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 Quality Payment Program final rule (81 FR 77825). We propose to modify this activity to include the opportunities for clinicians to fulfill this improvement activity by applying the quality, utilization, patient satisfaction, and other measures or quality improvement actions to address inequities in quality and outcomes for underserved populations, including racial, ethnic, and gender minorities. We also propose to improve the activity language in ways that clarify the activity, but do not affect its intent, including simplifying the first activity option by removing the language "that may be useful at the practice level and at the level of the care team or MIPS eligible clinician or group (panel)," since it is stated at the beginning of the description that these activities can take place at the practice and panel levels. We believe that participation in the modified version of this improvement activity would be more likely to result in improved outcomes, because clinicians who review these relevant data sources for particular underserved populations and create benchmarks and goals for improvement are likely to provide better quality and more equitable care.
Proposed Revised Activity Description:	Measure and improve quality at the practice and panel level, such as the American Board of Orthopaedic Surgery (ABOS) Physician Scorecards that could include one or more of the following: • Regularly review measures of quality, utilization, patient satisfaction and other measures; and/or • Use relevant data sources to create benchmarks and goals for performance at the practice or panel levels. Clinicians can apply the measurement and quality improvement to address inequities in quality and outcomes for underserved populations, including racial, ethnic, and/or gender minorities.
Current Improvement Activity	
Current Activity ID:	**IA_ERP_3**
Current Subcategory:	Emergency Response and Preparedness
Current Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Current Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data should be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of

	Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Weighting:	High
Proposed Action and Rationale:	We previously adopted this improvement activity to the inventory for the 2020 and 2021 MIPS performance periods only in response to the PHE for COVID-19 and planned to reassess its need for the 2022 MIPS performance period/2024 MIPS payment year and future years. We are now proposing to continue this improvement activity for the 2022 MIPS performance period/2024 MIPS payment year and future years. Despite increasing dissemination of COVID-19 vaccines, we anticipate that COVID-19 infections may continue to be prevalent in communities with low vaccine adoption and/or among groups (i.e., children) who do not yet have access to vaccines. Additionally, new variants of COVID may introduce additional challenges to the eradication and treatment of the illness. Due to these concerns, clinicians may likely continue to encounter COVID-19 patients, and therefore we anticipate the need for COVID-19 clinical trials and data collection/sharing through registries to continue through CY 2022 and future years. Each year we will reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We want eligible clinicians to be able to attest to this improvement activity if it is still pertinent. If this improvement activity becomes no longer needed, we will remove the activity through rulemaking. While COVID-19 continues to be a PHE and a great concern for clinicians, patients, and communities, we believe that continued participation in this improvement activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID-19. We note that the activity description would remain the same.

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TABLE C: Improvement Activities Proposed for Removal for the 2022 MIPS Performance Period/2024 MIPS Payment Year and Future Years

In this rule, we are proposing to remove six previously finalized improvement activity from the MIPS Program for the 2022 MIPS performance period/2024 MIPS payment year and future years. These improvement activities are discussed in detail below. Improvement activity removal factors are discussed in the MIPS CY 2020 final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_ BE_13**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms
Current Activity Description:	Regularly assess the patient experience of care through surveys, advisory councils and/or other mechanisms.
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_13 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_6. In this proposed rule, we are proposing to consolidate the unique language from IA_BE_13 into IA_BE_6 per the proposed changes in Table B. The proposed revised IA_PM_6 adds additional detail from IA_BE_13 (e.g., use of advisory councils). IA_BE_6 has a stronger relationship to improvement in clinical practice because it also requires the development of an improvement plan based on the results of the patient experience data gathered and assessed. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_6 in Table B, as well as our proposal to remove IA_PSPA_11 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_11**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in CAHPS or other supplemental questionnaire
Current Activity Description:	Participation in the Consumer Assessment of Healthcare Providers and Systems Survey or other supplemental questionnaire items (e.g., Cultural Competence or Health Information Technology supplemental item sets).
Current Weighting:	High
Removal Rationale:	We are proposing to remove this activity under removal factor 1, improvement activity is "duplicative." We believe IA_PSPA_11 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_6. In this proposed rule, we are proposing to consolidate the unique language from IA_PSPA_11 into IA_BE_6 per the proposed change in Table B. The proposed revised IA_BE_6 adds additional detail from IA_PSPA_11 (e.g., CAHPS). We note that this proposed removal is made in conjunction with our proposal to change IA_BE_6 in Table B, as well as our proposal to remove IA_BE_13 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_BE_17**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Use of tools to assist patient self-management
Current Activity Description:	Use tools to assist patients in assessing their need for support for self-management (e.g., the Patient Activation Measure or How's My Health).
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_17 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. In this proposed rule, we are proposing to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_17 (e.g., Patient Activation Measure). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice, because it emphasizes the incorporation of new tools and techniques into routine care processes.

	We note that this proposed removal is made in conjunction with our proposal to change IA_BE_16 in Table B, as well as our proposals to remove IA_BE_18, IA_BE_20, and IA_BE_21 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_BE_18**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Provide peer-led support for self-management.
Current Activity Description:	Provide peer-led support for self-management.
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_18 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. In this proposed rule, we are proposing to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_18 (e.g., peer-led support for self-management). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal is made in conjunction with our proposal to modify IA_BE_16 in Table B, as well as our proposals to remove IA_BE_17, IA_BE_20, and IA_BE_21 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_BE_20**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Implementation of condition-specific chronic disease self-management support programs
Current Activity Description:	Provide condition-specific chronic disease self-management support programs or coaching or link patients to those programs in the community.
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_20 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. In this proposed rule, we are proposing to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_20 (e.g., condition-specific chronic disease self-management support programs). Proposed modified IA_BE_16 has a stronger relationship to improvement in clinical practice because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_16 in Table B, as well as our proposals to remove IA_BE_17, IA_BE_18, and IA_BE_21 in Table C.
Current Improvement Activity	
Current Activity ID:	**IA_BE_21**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Improved practices that disseminate appropriate self-management materials
Current Activity Description:	Provide self-management materials at an appropriate literacy level and in an appropriate language.
Current Weighting:	Medium
Removal Rationale:	We are proposing to remove this activity under removal factor 1, improvement activity is "duplicative" and removal factor 2, there is an alternative activity with a stronger relationship to quality care or improvements in clinical practice. We believe IA_BE_21 is duplicative, because it is similar to, but only represents a partial component of proposed modified IA_BE_16. In this proposed rule, we are proposing to consolidate the unique language from IA_BE_17, IA_BE_18, IA_BE_20, and IA_BE_21 into IA_BE_16 per the proposed change in Table B. The proposed revised IA_BE_16 adds additional detail from IA_BE_21 (e.g., provision of appropriate self-management materials). Proposed modified IA_BE_16 has a stronger relationship to improvement in

	clinical practice because it emphasizes the incorporation of new tools and techniques into routine care processes. We note that this proposed removal is made in conjunction with our proposal to change IA_BE_16 in Table B, as well as our proposals to remove IA_BE_17, IA_BE_18, and IA_BE_20 in Table C.

Appendix 3: Mvp Inventory

MVP Development Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), we finalized a set of criteria to be used in the development of MVPs. In addition, in section IV.A.3.b of this proposed rule, we discuss additional proposed MVP policies, including MVP reporting requirements and selection of measures and activities within an MVP.

This appendix includes seven proposed MVPs for implementation beginning with the CY 2023 MIPS performance period/2025 MIPS payment year.[268] Each proposed MVP includes measures and activities from the quality performance category, improvement activities performance category, and the cost performance category that are relevant to the clinical theme of the MVP. In addition, as described in the CY 2021 PFS final rule (85 FR 84841) and section IV.A.3.b.(4)(b)(i)(C) of this proposed rule, all proposed MVPs include a foundational layer, which is comprised of population health measures and Promoting Interoperability performance category measures. We refer readers to section IV.A.3.b.(4)(b)(i) of this proposed ruled for key considerations and overall development approach for proposing the MVPs included in this appendix. For additional details regarding the proposed annual maintenance process for MVPs, we refer readers to section IV.A.3.b.(4)(b)(ii) of this proposed rule.

MVP Development Performance Category Sources

The MVP tables proposed below contain a set of MIPS quality measures, QCDR measures, improvement activities, cost measures, and foundational measures based on clinical topics. For further reference, the sources of the measures and activities in the MVP tables are as follows:

- Existing MIPS quality measures considered in developing the MVPs are located in Appendix 1: MIPS Quality Measures of this proposed rule.
- Existing QCDR measures considered in developing the MVPs were based on the most recent publication of the 2021 QCDR Measure Specification file. The QCDR measures are listed in the 2021 QCDR Measure Specification file located in the QPP Resource Library.[269] An updated list of 2022 QCDR measures will be available in December 2021.
- Improvement activities considered in developing the MVPs are located in the 2021 Improvement Activities Inventory and the 2021 MIPS Data Validation Criteria located in the QPP Resource Library.[270]
- Existing cost measures considered in developing the MVPs are located in the CY 2020 PFS final rule (84 FR 62979).
- For further details on the proposed new episode-based cost measures, refer to section IV.A.3.d.(2)(b) of this proposed rule.
- For further details on the population health measures included in the foundational layer, refer to section IV.A.3.b.(4)(b)(i)(C)(aa)of this proposed rule.
- Existing Promoting Interoperability measures adopted in prior rulemaking and included in the foundational layer are located in the QPP Resource Library.[271] In addition, see section IV.A.3.d.(4)(c) for any proposed modifications to the existing Promoting Interoperability measures.

Please note that new quality and Promoting Interoperability measures proposed for inclusion in MIPS beginning with the CY 2022 MIPS performance period/2024 MIPS payment year are identified with a caret symbol (^) within the MVP tables in this appendix. In addition, existing quality measures and improvement activities with proposed revisions are identified with an asterisk (*) before the quality measure or improvement activity ID # within the MVP tables in this appendix. See Appendix 1: MIPS Quality Measures and Appendix 2: Improvement Activities for further details regarding the proposed substantive changes and revisions in this proposed rule.

Quality measures that are considered high priority are noted with an exclamation point (!) and outcome measures are noted with a double exclamation point (!!). Quality measure collection types are identified in parentheses after each quality measure title within each MVP table.

QCDR measures proposed in the MVP tables below are noted with a pound sign (#) to indicate that testing data is pending on or before September 1, 2021. In order to determine whether a QCDR measure may be finalized within an MVP, we will need to receive QCDR measure testing data for review by the end of the self-nomination period (i.e., no later than September 1 of the year prior to the applicable performance period). We strongly encourage that QCDRs share testing data for their fully tested QCDR measures at the time of MVP candidate submission, which may be prior to the September 1st deadline. If a QCDR is unable to submit testing data to demonstrate that their QCDR measure is fully tested by the end of the self-nomination period (September 1st), or otherwise does not meet our requirements, we will not finalize the inclusion of the QCDR measure within an MVP. We refer

[268] See section IV.A.3.b.(2)(d) of this proposed rule for additional details regarding the MVP implementation timeline.
[269] See https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1231/2021%20QCDR%20Measure%20Specifications.xlsx for QCDR measures.
[270] See the 2021 Improvement Activities Inventory: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1189/2021%20Improvement%20Activities%20List.zip 2021 MIPS Data Validation Criteria: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1316/2021%20MIPS%20Data%20Validation%20Criteria.zip for improvement activity details.
[271] See the 2021 MIPS Promoting Interoperability Measure Specifications: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1260/2021%20MIPS%20Promoting%20Interoperability%20Measure%20Specifications.zip for Promoting Interoperability measure details.

readers to section IV.A.3.b.(4)(b)(i) of this proposed rule for additional details regarding QCDR measures and selection of measures within an MVP.

In addition, consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government," each MVP includes improvement activities designed to advance health equity and address and eliminate barriers to care in underserved communities.[272] Improvement activities that include a health equity component are noted with a tilde (~) before the improvement activity ID # within the MVP table. Improvement activity medium/high weight designations are identified in parentheses after each improvement activity. IA_PCMH is noted with a percent (%) before the improvement activity ID # within the MVP tables below to indicate that attestation to this improvement activity would provide full credit for the improvement activities performance category within the MVP.

[272] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

Table A: Proposed Advancing Rheumatology Patient Care MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Rheumatic diseases are comprised of complex chronic autoimmune and inflammatory conditions that affect joints, bones, muscles, and organs, which may eventually lead to poor outcomes and disability in patients if not well-controlled. Timely and appropriate care is critically important to the long-term health of patients. The proposed Advancing Rheumatology Patient Care MVP focuses on the clinical theme of providing fundamental treatment and management of rheumatological conditions and is most applicable to clinicians who specialize in treating patients with rheumatologic conditions.

Quality Measures

Within the quality component of this MVP, we propose to include six MIPS quality measures and three QCDR measures, which promote the assessment and control of rheumatic diseases to reduce the risk of disability and disease-related complications. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with rheumatologic conditions:

- Q176: Tuberculosis Screening Prior to First Course Biologic Therapy: This MIPS quality measure addresses the aspect of screening for tuberculosis (TB) prior to prescribing a biologic disease-modifying anti-rheumatic (DMARD) therapy. This is especially important as patients administered DMARD therapy are at higher risk for TB infection.
- Q177: Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity: This MIPS quality measure is important for monitoring RA disease activity to facilitate timely and appropriate, optimal treatment for patients.
- Q178: Rheumatoid Arthritis (RA): Functional Status Assessment: This MIPS quality measure examines for evidence of symptoms that may limit or disrupt the patient's quality of life.
- Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management: This MIPS quality measure addresses the need to closely monitor patients who receive glucocorticoid as a part of their rheumatologic care, in order to avoid potential complications. Glucocorticoid therapy is highly effective treatment for relieving symptoms in patients with RA.
- ACR12: Disease Activity Measurements for Patients with PsA: This QCDR measure promotes regular assessment of functional limitations and disease activity for treatment planning and clinical decision making for patients with psoriatic arthritis (PsA).
- ACR14: Gout Serum Urate Target: This QCDR measure is an outcome that assesses the control of gout by assessing control of serum urate levels. This relevant measure helps clinicians evolve to patient-centered, evidence-driven best practices.
- ACR15: Safe Hydroxychloroquine Dosing: This QCDR measure addresses the need to closely monitor patients who receive dosing of hydroxychloroquine as a part of their rheumatologic care, in order to avoid potential complications.

In conjunction with the aforementioned rheumatologic specific measures, we propose to include the following broadly applicable MIPS quality measures that are relevant to rheumatic disease care:

- Q111: Pneumococcal Vaccination Status for Older Adults: This MIPS quality measure has been included to ensure that pneumococcal vaccinations are comprehensively assessed and used. Vaccinations play an important role in the management of patients with rheumatological conditions who are at an increased risk for infections because of their underlying condition, comorbidities, and use of immunosuppressive therapies.
- Q130: Documentation of Current Medications in the Medical Record: This MIPS quality measure promotes care coordination to collect complete and reliable medication records.

Only one MIPS vaccination quality measure was included within this MVP. We selected Q111: Pneumococcal Vaccination Status for Older Adults rather than Q110: Preventive Care and Screening: Influenza Immunization because it is more relevant to the Rheumatology MVP. Q111 focuses on the prevention of pneumonia, which is a common cause of illness and death for patients with underlying conditions and those being treated with immunosuppressive therapies.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include 11 improvement activities that reflect actions and processes undertaken by clinicians who provide rheumatic care to patients. These improvement activities provide an opportunity for meaningful improvement and patient engagement for clinicians who specialize in treating patients with rheumatologic conditions. Therefore, the following improvement activities are proposed for inclusion in this MVP:

- IA_AHE_3: Promote use of Patient-Reported Outcome Tools: Utilization of patient-reported outcome tools often helps clinicians make decisions about the best course of care and which patients may benefit from a particular intervention.
- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care: Patient engagement while developing a plan of care is a key element of general adherence to the overall care plan established by the clinician for the rheumatologic patient population.
- IA_PM_16: Implementation of medication management practice improvements: Reliable medication records are essential for the care of rheumatology patients, as medication-based therapies may consist of various classes of agents (for example, nonsteroidal anti-inflammatory drugs [NSAIDS], corticosteroids) to slow the progression of rheumatologic disease.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional

opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for rheumatology patients:

- IA_BE_1: Use of certified EHR to capture patient reported outcomes
- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BMH_2: Tobacco use
- IA_BMH_4: Depression screening
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_EPA_2: Use of telehealth services that expand practice access
- IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program
- IA_PSPA_28: Completion of an Accredited Safety or Quality Improvement Program

Cost Measures

Within the cost component of this MVP, we propose the Total Per Capita Cost (TPCC) measure because it captures the overall costs of care after establishing a primary care relationship, including the care provided by rheumatologists. The TPCC measure focuses on the ongoing management of rheumatology conditions and aligns with the intent of this MVP. We considered including the Medicare Spending Per Beneficiary (MSPB) Clinician measure, but ultimately did not include it because it only focuses on inpatient care. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future. Refer to section IV.A.3.d.(2) of this proposed rule for details on the current cost measure development process and potential cost measure development process that could lead to an episode-based measure related to this MVP.

TABLE A: Proposed Advancing Rheumatology Patient Care MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Advancing Rheumatology Patient Care MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(*) Q111: Pneumococcal Vaccination Status for Older Adults (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!) Q130:** Documentation of Current Medications in the Medical Record (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q176:** Tuberculosis Screening Prior to First Course Biologic Therapy (MIPS CQMs Specifications) **Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (MIPS CQMs Specifications) **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment (MIPS CQMs Specifications) **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management (MIPS CQMs Specifications) **ACR12:** Disease Activity Measurements for Patients with PsA (QCDR) **(!!)(#) ACR14:** Gout Serum Urate Target (QCDR) **(!)(#) ACR15:** Safe Hydroxychloroquine Dosing (QCDR)	**(~) IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(*)(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_BMH_4:** Depression screening (Medium) **(*)(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(*)IA_EPA_2:** Use of telehealth services that expand practice access (Medium) **IA_PM_16:** Implementation of medication management practice improvements (Medium) **(*)IA_PSPA_6:** Consultation of the Prescription Drug Monitoring Program (High) **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) **(^)(!!) TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting**	

	Clinical Data Registry Reporting **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

Table B: Proposed Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Cerebral infarction, or stroke, is the 9th most expensive condition treated in United States hospitals.[273] According to the Centers for Disease Control and Prevention (CDC), "more than 868,000 Americans die of heart disease or stroke every year—one-third of all deaths."[274] The proposed Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP focuses on the clinical theme of providing fundamental prevention and treatment of those patients at risk for or that have had a stroke. This proposed MVP would be most applicable to clinicians who treat clinically varied patient types within the practice of neurology and vascular surgery.

Quality Measures

Within the quality component of this MVP, we propose to include nine MIPS quality measures, which focus on both stroke prevention and driving positive outcomes for the stroke patient population. We reviewed the MIPS quality measure inventory and believe the quality measures proposed within this MVP below provide a meaningful and comprehensive stroke prevention and intervention set.

This MVP includes the following measures that support the goal of reducing the risk of stroke:

- Q236: Controlling High Blood Pressure: This MIPS quality measure requires controlled blood pressure for patients diagnosed with hypertension which leads to better health outcomes including reducing the risk of stroke.
- Q326: Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy AND Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: These MIPS quality measures were included to ensure patients at an increased risk of stroke receive the appropriate preventive medication regimen. The use of statin therapy reduces the risk of atherosclerotic cardiovascular disease (ASCVD). The use of an anticoagulant will reduce risk of thromboembolism occurring with atrial fibrillation which is associated with a greater risk of recurrent stroke, more severe disability, and mortality.
- Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2): This MIPS quality outcome measure promotes appropriate selection of patients for this procedure by assessing percentage of patients discharged to home no later than post-operative day two. Patients at low risk for morbidity, with a surgeon who performs the procedure with a very low complication rate, achieve the benefit of reduction of long-term risk of stroke.
- Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control): This MIPS quality measure supports the mitigation of stroke risk for patients with established ischemic vascular disease with quality actions that promote blood pressure control, tobacco free status, patient use of daily aspirin, and use of statin which captures the clinical concepts represented in the Million Hearts® Initiative.

For those patients who do suffer a stroke, this MVP drives timely treatment to drive quality and cultivate positive outcomes with the inclusion of the following measures:

- Q187: Stroke and Stroke Rehabilitation: Thrombolytic Therapy: This MIPS quality measure drives careful screening and timely treatment to promote better outcomes for patients with a stroke diagnosis.
- Q409: Clinical Outcome Post Endovascular Stroke Treatment: This MIPS quality measure utilizes the modified Rankin scale (mRs) to assess degree of disability or dependence in the daily activities of patients suffering a stroke. An mRs of 2 or less after endovascular therapy is considered an excellent outcome following a stroke.
- Q413: Door to Puncture Time for Endovascular Stroke Treatment: This MIPS quality measure drives efficiency so that stroke patients are given the best chance of functional recovery by ensuring door to puncture time is less than 90 minutes.

We understand that the two time-dependent measures (Q187 and Q413) may place small and rural practices at a disadvantage as they may not have the resources to implement rapid stroke response systems; however, MVPs allow for some clinician choice with regards to quality measure submission, which would allow those small and rural practices to select other quality measures to meet the quality reporting requirements described in section IV.A.3.b.(4)(d) of this proposed rule.

In conjunction with the aforementioned stroke and stroke prevention quality measures, we propose to include the following broadly applicable quality measure that is relevant to stroke care:

- Q047: Advance Care Plan: The inclusion of this MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.

We considered including Q260: Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2) within the MVP. However, we determined that Q344: Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) was more appropriate because CAS may be utilized more often in the asymptomatic patient population.

[273] https://www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.jsp.
[274] https://www.cdc.gov/chronicdisease/about/costs/index.htm#ref1.

Additionally, trial results have shown CAS to be an effective CEA alternative for high-risk surgical patients, allowing the measure to indicate both appropriateness of use and overall outcome. Therefore, we believe the patient population for Q344 will be more encompassing; consequently, the inclusion of this measure will make this MVP more applicable to a broader set of clinicians and allow them to select the most meaningful quality measures.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include nine improvement activities that reflect actions and processes undertaken by clinicians working to coordinate meaningful stroke care and prevention. We have reviewed the MIPS improvement activity inventory and believe the improvement activities proposed within this MVP provide an opportunity for meaningful improvement and patient engagement for clinicians who treat patients at risk for or who have had a stroke. Therefore, the following improvement activities are proposed for inclusion in this MVP:

- IA_PM_13: Chronic care and preventative care management for empaneled patients: This improvement activity reflects opportunities for clinicians to coordinate meaningful stroke care and prevention within an empaneled support network.
- IA_PM_15: Implementation of episodic care management practice improvements AND IA_BE_4: Engagement of patients through implementation of improvements in patient portal: Promotes patient engagement in their own care and provides an opportunity for the patient to connect with others recovering from or at risk for stroke to improve their outcomes.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for stroke patients:

- IA_BE_1: Use of certified EHR to capture patient reported outcomes
- IA_BE_24: Financial Navigation Program
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_13: Practice improvements for bilateral exchange of patient information
- IA_CC_17: Patient Navigator Program
- IA_PCMH: Implementation of Patient-Centered Medical Home model

Cost Measures

Within the cost component of this MVP, we propose the Intracranial Hemorrhage or Cerebral Infarction episode-based measure because it focuses on the costs related to inpatient clinicians' treatment for the following types of stroke: intracerebral or subdural hemorrhage, and cerebral infarction. The TPCC measure was considered but not included in this MVP since the neurology specialty is excluded from the TPCC measure attribution. We considered including the MSPB Clinician measure but ultimately did not include it as it encompasses all inpatient care, rather than focusing on the specific costs related to stroke.

TABLE B: Proposed Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(!) Q047: Advance Care Plan (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (MIPS CQMs Specifications) **(*)(!!) Q236:** Controlling High Blood Pressure (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*) Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) **(!!) Q344:** Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (MIPS CQMs Specifications) **(*)(!!) Q409:** Clinical Outcome Post Endovascular Stroke Treatment (MIPS CQMs Specifications) **(*)(!!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (eCQM Specifications, MIPS CQMs Specifications) **(!!) Q441**: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (MIPS CQMs Specifications)	**(*)(~) IA_BE_1:** Use of certified EHR to capture patient reported outcomes (Medium) **IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **IA_CC_17:** Patient Navigator Program (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PM_13:** Chronic care and preventative care management for empaneled patients (Medium) **IA_PM_15:** Implementation of episodic care management practice improvements (Medium)	**Intracranial Hemorrhage or Cerebral Infarction**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) (^)(!!) **TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

Table C: Proposed Advancing Care for Heart Disease MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Heart disease cost the United States about $219 billion each year from 2014 to 2015, including the cost of health care services, medicines, and lost productivity due to death.[275] Additionally, heart disease can lead to serious illness, disability, lower quality of life, and may be fatal.[276] The proposed Advancing Care for Heart Disease MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, heart disease. This proposed MVP would be most applicable to clinicians who treat clinically varied patient types within the practice of cardiology.

Quality Measures

Within the quality component of this MVP, we propose to include eight MIPS quality measures, which promote the management and risks associated with heart disease. We believe this MVP will support the improvement of patient symptoms with disease management and mitigation of clinical risk which contribute to heart disease. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with conditions related to heart disease conditions:

- Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD): This MIPS quality measure addresses the use of ACE, ARB, or ARNI pharmacological therapy to reduce the clinical symptoms of heart failure, reduce the risks of morbidity, and mortality.
- Q007: Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%): This MIPS quality measure addresses the use of beta-blocker pharmacological therapy to reduce the potential of cardiovascular hospitalizations and revascularization intervention. Additionally, the use of this therapy may reduce angina symptoms for patients.
- Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): This MIPS quality measure addresses the use of beta-blocker pharmacological therapy to reduce the clinical symptoms of heart failure, reduce the risks of morbidity, and mortality.
- Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting: This MIPS quality measure supports the use of cardiac rehabilitation, to support the reduction of morbidity and mortality, for patients that have experienced an event related to coronary artery disease. NQF 0642: Cardiac Rehabilitation Referral from an Inpatient Setting may be an option for this MVP for future program years. In order for this measure to be considered it would need to be available as a MIPS quality measure.
- Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control): This MIPS quality measure supports the mitigation of risk for patients with established coronary artery disease (CAD) with quality actions that promote blood pressure control, tobacco free status, patient use of daily aspirin, and use of statin which captures the clinical concepts represented in the Million Hearts® Initiative. Despite the title of the measure encompassing all ischemic vascular disease, this MIPS quality measure includes the coding to support patients specifically diagnosed with CAD.

In conjunction with the aforementioned heart disease specific measures, we propose to include the following broadly applicable quality measures that are relevant to heart disease care:

- Q047: Advance Care Plan: The inclusion of this MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure addresses the assessment of body mass index (BMI) and maintenance of a healthy body weight. Specifically, it will support the assessment and follow up plan for those patients identified with having a high BMI which is a risk factor of heart disease.
- Q238: Use of High-Risk Medications in Older Adults: This MIPS quality measure supports patient safety by assessing for the use of high-risk medications.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include 11 improvement activities that reflect actions and processes undertaken by clinicians working to improve care for patients with heart disease. We have reviewed the MIPS improvement activity inventory and believe the improvement activity proposed within this MVP provides an opportunity for meaningful improvement and patient engagement for clinicians who specialize in managing risks and treating patients with heart disease. Therefore, the following improvement activity is proposed for inclusion within this MVP:

- IA_BE_15: Engagement of patients, family and caregivers in developing a plan of care: Drives the urgency of an "informed active patient" and the need to establish communication of healthcare goals and objectives with a proactive team for better health outcomes.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional

[275] https://www.cdc.gov/heartdisease/facts.htm#:~:text=Heart%20Disease%20in%20the%20United%20States&text=Heart%20disease%20costs%20the%20United,year%20from%202014%20to%202015.

[276] https://millionhearts.hhs.gov/learn-prevent/cost-consequences.html.

opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients experiencing symptoms of and/or managing heart disease:

- IA_BE_12: Use evidence-based decision aids to support shared decision-making
- IA_BE_24: Financial Navigation Program
- IA_BE_25: Drug Cost Transparency
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_EPA_4: Additional improvements in access as a result of QIN/QIO TA
- IA_PM_14: Implementation of methodologies for improvements in longitudinal care management for high risk patients
- IA_PSPA_4: Administration of the AHRQ Survey of Patient Safety Culture
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_30: PCI Bleeding Campaign

Cost Measures

Within the cost component of this MVP, we propose the Elective Outpatient Percutaneous Coronary Intervention (PCI) and ST Elevation Myocardial Infarction (STEMI) with PCI episode-based measures, as well as the TPCC measure. All three of these cost measures capture costs of care related to the practice of cardiology. The two episode-based measures assess costs related to PCI: the first, Elective Outpatient PCI, focuses on the specific outpatient procedure as a common procedure that is important for the treatment of stable and urgent coronary artery disease. The second, STEMI with PCI, focuses on inpatient care for severe heart attack. In addition, the TPCC measure assesses the total costs of care after identifying the start of a clinician-patient relationship, including cardiologists. The TPCC measure is appropriate given its broader focus on the ongoing costs of care, similar to the quality measures in this MVP. This range of cost measures aligns with the broad focus of the MVP to apply to clinicians providing care to patients with heart disease. We considered including the MSPB Clinician measure, but ultimately did not include it because it encompasses all inpatient care, rather than focusing on the specific costs related to cardiology.

TABLE C: Proposed Advancing Care for Heart Disease MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Advancing Care for Heart Disease MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(*) **Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (eCQM Specifications, MIPS CQMs Specifications) (*) **Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%) (eCQM Specifications, MIPS CQMs Specifications) (*) **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (eCQM Specifications, MIPS CQMs Specifications) (!) **Q047:** Advance Care Plan (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (*) **Q128**: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) (*)(!) **Q238:** Use of High-Risk Medications in Older Adults (eCQM Specifications, MIPS CQMs Specifications) (!) **Q243:** Cardiac Rehabilitation Patient Referral from an Outpatient Setting (MIPS CQMs Specifications) (!!) **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (MIPS CQMs Specifications)	**IA_BE_12:** Use evidence-based decision aids to support shared decision-making (Medium) **IA_BE_15:** Engagement of patients, family and caregivers in developing a plan of care (Medium) **IA_BE_24:** Financial Navigation Program (Medium) **IA_BE_25:** Drug Cost Transparency (High) (~) **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) (*)(~) **IA_CC_14:** Practice improvements that engage community resources to support patient health goals (high) **IA_EPA_4:** Additional improvements in access as a result of QIN/QIO TA (Medium) **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients (Medium) **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture (Medium) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_30:** PCI Bleeding Campaign (High)	**Elective Outpatient Percutaneous Coronary Intervention (PCI)** **ST Elevation Myocardial Infarction (STEMI) with PCI** **Total Per Capita Cost (TPCC)**

Foundational Layer	
Population Health Measures	**Promoting Interoperability**
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) (^)(!!) **TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting**

	Security Risk Analysis **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

Table D: Proposed Optimizing Chronic Disease Management MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Chronic disease represents 90% of the nation's $3.8 trillion in annual health care expenditures for people with chronic and mental health conditions.[277] The proposed Optimizing Chronic Disease Management MVP focuses on the clinical theme of providing fundamental treatment and management of chronic disease such as diabetes, coronary artery disease, chronic obstructive disease, and major adult depression. This MVP would be most applicable to clinicians who treat clinically varied patient types with those chronic clinical conditions including but not limited to family practice, internist, or geriatric care.

Quality Measures

Within the quality component of this MVP, we propose to include nine MIPS quality measures which focus on a variety of chronic conditions that may impact overall patient health. There may be instances in which a patient could be diagnosed with multiple chronic conditions impacting everyday activities of daily living. In order to preserve clinician choice, we included quality measures that were determined to be priority areas within chronic disease management. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with chronic conditions:

- Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy: This MIPS quality measure addresses the use of antiplatelet therapy for patients diagnosed with CAD. Antiplatelet therapy use has shown to reduce the occurrence of vascular events for patients experiencing CAD.
- Q107: Adult Major Depressive Disorder (MDD): Suicide Risk Assessment: This MIPS quality measure supports assurance that a suicide risk assessment is completed once a patient has a new diagnosis or recurrent episode with MDD.
- Q118: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%): This MIPS quality measure addresses the use of ACE or ARB pharmacological therapy to reduce the clinical symptoms of heart failure, reduce the risks of morbidity and mortality in patients with CAD and/or diabetes.
- Q119: Diabetes: Medical Attention for Nephropathy: This MIPS quality measure supports screening for or evidence of nephropathy. High blood sugar levels in patients with diabetes put them at a higher risk of damaging their kidneys and causing chronic kidney disease, which can lead to kidney failure.
- Q236: Controlling High Blood Pressure: This MIPS quality measure promotes the quality action maintaining a patient blood pressure to maintain a systolic pressure of < 140 mmHg and diastolic pressure of < 90 mmHg. Controlling HBP will significantly reduce the risks of cardiovascular disease mortality and lead to better health outcomes like reduction of heart attacks, stroke, and kidney disease.
- Q398: Optimal Asthma Control: This MIPS quality composite measure evaluates pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age-appropriate patient reported outcome tools and assesses risk of exacerbation.
- Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: The MIPS quality action represented within this quality measure is the prescription or maintenance of statin therapy. The use of statin therapy reduces the risk of atherosclerotic cardiovascular disease (ASCVD).

In conjunction with the aforementioned chronic disease management specific measures, we propose to include the following broadly applicable quality measures that are relevant to chronic disease management:

- Q047: Advanced Care Plan: The inclusion of this MIPS quality measure captures the clinical interaction of documenting a patient's voice for possible, future life-sustaining medical intervention. This engagement between the clinician (or clinician staff) and the patient allows the patient to be autonomous and communicate their ideal of clinical care that ensures coordinated care is implemented as documented in the patient's medical record.
- TBD: Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure: This MIPS quality measure represents a comprehensive set of patient-clinician interaction assessments within the broad scope of primary care. This quality measure focuses on a patient's relationship with the clinician or practice.

The following quality measures were considered for this proposed MVP but not included based on the rationales below:

- Q052: Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator was considered; however, Q398 was selected because we believe the clinical concept represented within Q398 is more appropriate as it supports a broader age range of patients and promotes improved outcomes in asthma management.
- Q321: Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey was considered; however, we selected the newly proposed MIPS measure TBD: Person-Centered Primary Care Measure Performance Measure (PCPCM PRO-PM) because we want to capture the patient experience, but limit to one quality measure capturing patient voice.
- Q370: Depression Remission at Twelve Months was considered; however, Q107 was selected because we felt it was important to focus on suicide prevention as it is the 10th leading cause of death in the United States[278]. Although we acknowledge it is important to work towards remission for those patients that suffer from depression, we believe that

[277] https://www.cdc.gov/chronicdisease/about/costs/index.htm.

[278] Mortality in the United States, 2019 NCHS Data Brief No. 395 Kenneth D. Kochanek, M.A., Jiaquan Xu, M.D., and Elizabeth Arias, Ph.D. https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm.

ongoing suicide risk assessments for those patients with new or ongoing major depressive disorder is a more critical health priority.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include 12 improvement activities that reflect actions and processes undertaken by clinicians working to optimize chronic disease management for their patient populations. We have reviewed the MIPS improvement activity inventory and believe the improvement activities proposed within this MVP provide an opportunity for meaningful improvement and patient engagement for clinicians who focus on a variety of chronic conditions that may impact overall patient health. Therefore, the following improvement activities are proposed for inclusion within this MVP:

- IA_BE_4: Engagement of patients through implementation of improvements in patient portal: Promotes the use of patient portals for the treatment of chronic disease, such as diabetes and leads to better medication adherence and overall chronic disease management.
- IA_BE_21: Improved Practices that Disseminate Appropriate Self-Management Materials: Promotes the use of clinical literature to inform patients of evidenced-based approaches to self-management for the treatment of chronic disease.
- IA_CC_13: Practice improvements for bilateral exchange of patient information: A core component of patient safety, contributing to the reduction of medication errors and patient harm. Additionally, bilateral exchange assists caregivers with relevant clinical decision support and enhances public health reporting initiatives.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients diagnosed with chronic conditions:

- IA_AHE_3: Promote use of Patient-Reported Outcome Tools
- IA_BE_20: Implementation of condition-specific chronic disease self-management support programs
- IA_BE_22: Improved practices that engage patients pre-visit
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_12: Care coordination agreements that promote improvements in patient tracking across settings
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_PCMH: Implementation of Patient-Centered Medical Home model
- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes

Cost Measures

Within the cost component of this MVP, we propose the TPCC measure because it focuses on the total cost of primary care including ongoing care for major chronic comorbidities after identifying the start of a clinician-patient relationship. The TPCC measure aligns with the types of care being assessed by the quality measures and improvement activities within this MVP. We considered including the MSPB Clinician measure, but ultimately did not include it because the measure applies only to inpatient care and does not align with the types of care envisaged by this MVP. Currently, there are no applicable episode-based measures available for this MVP, but the addition and/or development of applicable episode-based measures could be considered in the future. Refer to section IV.A.3.d.(2) of this proposed rule for details on two chronic condition episode-based measures which focus on asthma/COPD and diabetes that are being proposed for use in the Cost performance category in this proposed rule and could be applicable to this MVP in a future rulemaking cycle.

TABLE D: Proposed Optimizing Chronic Disease Management MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Optimizing Chronic Disease Management MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
Q006: Coronary Artery Disease (CAD): Antiplatelet Therapy (MIPS CQMs Specifications) **(!) Q047**: Advance Care Plan (Medicare Part B Claims, MIPS CQMs Specifications) **Q107:** Adult Major Depressive Disorder (MDD): Suicide Risk Assessment (eCQM Specifications) **Q118**: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (MIPS CQMs Specifications) **(*) Q119**: Diabetes: Medical Attention for Nephropathy (eCQM Specifications, MIPS CQMs Specifications) **(*)(!!) Q236**: Controlling HIgh Blood Pressure (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(!!) Q398:** Optimal Asthma Control (MIPS CQMs Specifications) **(*) Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (eCQM Specifications, MIPS CQMs Specifications) **(^)(!!) TBD:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM (MIPS CQMs Specifications)	**(~) IA_AHE_3**: Promote use of Patient-Reported Outcome Tools (High) **IA_BE_4**: Engagement of patients through implementation of improvements in patient portal (Medium) **(*) IA_BE_20**: Implementation of condition-specific chronic disease self-management support programs (Medium) **(*) IA_BE_21**: Improved Practices that Disseminate Appropriate Self-Management Materials (Medium) **IA_BE_22**: Improved practices that engage patients pre-visit (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings (Medium) **IA_CC_13**: Practice improvements for bilateral exchange of patient information (Medium) **(*)(~) IA_CC_14:** Practice improvements that engage community resources to support patient health goals (Medium) **(*)(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (High) **(%) IA_PCMH:** Implementation of Patient-Centered Medical Home model **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium)	**Total Per Capita Cost (TPCC)**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) **(^)(!!) TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting**	

	Syndromic Surveillance Reporting **Electronic Case Reporting** **Public Health Registry Reporting** **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

Table E: Proposed Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Emergency Medicine treatment of high frequency pain conditions have considerable influence on healthcare quality and cost.[16] There is significant variation in admission decision rates for conditions including chest pain and abdominal pain.[279] Opportunities for advancement also exist for headache and back pain within the Emergency Department (ED), which identify significant clinician variation in opioid prescribing and imaging utilization for these clinical conditions.[280] The measure topics addressed in this proposed MVP fall within the Center for Disease Control and Prevention (CDC) National Hospital Ambulatory Medical Care Survey (NHAMCS) 2017 ED Summary tables, which list the top eight principal reasons for visiting the ED.[281] The proposed Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP focuses on important assessors of the care emergency clinicians provide to patients with undifferentiated high-risk conditions. By focusing on these specific measures and activities, emergency clinicians can reduce clinical variability, improve the quality of emergency care and potentially lower costs. This MVP would be most applicable to clinicians who treat clinically varied patient types within the ED.

Quality Measures

Within the quality component of this MVP, we propose to include five MIPS quality measures and five QCDR measures, which focus on chest pain, abdominal pain, headache, and back pain which promotes assessment of the undifferentiated high-risk conditions seen with high frequency and specific to emergency medicine clinicians. The chosen quality measures address complementary clinical care opportunities by assessing appropriate imaging utilization, laboratory testing, and medication prescribing. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients in the ED:

- Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis: This MIPS quality measure promotes appropriate prescribing of antibiotics for patients with acute bronchitis. The overprescribing of antibiotics contributes to antibiotic drug resistance, potentially leading to patient harm.
- Q254: Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain: This MIPS quality measure addresses the use of ultrasound for detection of ectopic pregnancy for pregnant patients presenting with abdominal pain or vaginal bleeding. Early ultrasound can shorten the time to diagnosis and reduce the associated morbidity with a delay in diagnosis.
- Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse): This MIPS quality measure promotes appropriate prescribing of antibiotics for patients with viral sinusitis. The overprescribing of antibiotics contributes to antibiotic drug resistance, potentially leading to patient harm.
- Q415: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older: This MIPS quality measure promotes appropriate use of head CT utilization in the ED for adult patients that present with minor blunt head trauma. It ensures that clinicians are purposefully ordering these studies to reduce cost and unnecessary harm to the patient by limiting radiation exposure.
- ACEP21: Coagulation studies in patients presenting with chest pain with no coagulopathy or bleeding: This QCDR measure promotes appropriate care and testing for patients that present with chest pain. It ensures that clinicians are purposefully ordering these studies which may lead to significant reduction in resource utilization without any decrease in value of healthcare provided to the patient.
- ACEP50: ED Median Time from ED arrival to ED departure for all Adult Patients: This QCDR measure promotes improving ED productivity and efficiency by expediting evaluation and treatment of new patients. When treatment times are prolonged, delays in care can occur and patients are put at risk for increased morbidity and mortality.
- ACEP52: Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain: This QCDR measure addresses appropriate diagnostic imaging for patients presenting with low back pain. Diagnostic imaging does not reliably identify the cause of most back pain and does not improve clinical outcome or time to recovery. Unnecessary or routine imaging (X-ray, MRI, CT scans) for low back pain exposes patients to unnecessary harms such as radiation and referral for unnecessary treatment that increases healthcare costs.
- ECPR46: Avoidance of Opiates for Low Back Pain or Migraines: This QCDR measure promotes appropriate prescribing of opiates. Opioid pain medications are often inappropriately utilized for the treatment of migraine headaches and uncomplicated low back pain and over-prescribing of opioids has contributed to the opioid epidemic.
- ECPR55: Avoidance of Long-Acting (LA) or Extended-Release (ER) Opiate Prescriptions and Opiate Prescriptions for Greater Than 3 Days Duration for Acute Pain: This QCDR measure promotes appropriate prescribing of long-acting and extended-release opiates with the intent of reducing the potential for opioid use disorders. Poor prescribing practices and over-prescribing of opioids has contributed to the opioid epidemic. Long-acting opioid pain medications can increase the risk for physical dependence and opioid use disorders. This measure is intended to prevent inappropriate prescribing of opioids and reduce the associated potential for opioid use disorders.

In conjunction with the aforementioned ED specific measures, we propose to include the following broadly applicable quality measure that is relevant to care provided in the ED:

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[279] Ann Emerg Med. 2020 May;75(5):ti612-614. doi: 10.1016/j.annemergmed.2019.09.008. Epub 2019 Dec 3.
[280] West J Emerg Med. 2017 Oct;18(6):1135-1142. doi: 10.5811/westjem.2017.7.33306. Epub 2017 Sep 18.
[281] https://www.cdc.gov/nchs/data/nhamcs/web_tables/2017_ed_web_tables-508.pdf.

- Q321: CAHPS for MIPS Clinician/Group survey: This survey will provide direct input from patients and their experience regarding timely care, effective communication, shared decision making, care coordination, promotion of health and education, completion of health status/functionality, and courtesy of office staff.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include 10 improvement activities that reflect actions and processes undertaken by clinicians working to improve care processes associated with undifferentiated high-risk conditions. We have reviewed the MIPS improvement activity inventory and believe the improvement activities proposed within this MVP provide an opportunity for meaningful improvement and patient engagement specific to emergency medicine clinicians. Therefore, the following improvement activities are proposed for inclusion within this MVP:

- IA_PSPA_19: Implementation of formal quality improvement methods, practice changes or other practice improvement processes: Provides opportunities to address the challenges presented by patients with undifferentiated high-risk conditions in the emergency healthcare setting.
- IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes: Encourages the development of innovative strategies for addressing patients with undifferentiated high-risk conditions in emergency room scenarios presenting with diagnostic uncertainty.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients seen by emergency medicine clinicians for assessment of undifferentiated high-risk conditions:

- IA_BE_4: Engagement of patients through implementation of improvements in patient portal
- IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_14: Practice improvements that engage community resources to support patient health goals
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization
- IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_15: Implementation of Antimicrobial Stewardship Program (ASP)

Cost Measures

Within the cost component of this MVP, we propose the MSPB Clinician measure because it applies to care received in the inpatient setting and covers a small share of emergency medicine clinicians. The TPCC measure was considered but not included in this MVP because the TPCC cost measure focuses on primary care and ongoing clinician-patient relationships, which is not the nature of emergency medicine care; in addition, the emergency medicine specialty is excluded from the TPCC measure attribution. Currently, there are no applicable episode-based measures available for this MVP, but one could be considered for development in the future. Refer to section IV.A.3.d.(2)(c) of this proposed rule for details on the current cost measure development process and potential cost measure development process that could lead to an episode-based measure related to this MVP.

TABLE E: Proposed Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(*) **Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (MIPS CQMs Specifications) (*) **Q254:** Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain (Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications) (!) **Q321:** CAHPS for MIPS Clinician/Group survey (CAHPS Survey Vendor) (!) **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (MIPS CQMs Specifications) (*) **Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older (MIPS CQMs Specifications) (!)(#) **ACEP21:** Coagulation studies in patients presenting with chest pain with no coagulopathy or bleeding (QCDR) (!!)(#) **ACEP50:** ED Median Time from ED arrival to ED departure for all Adult Patients (QCDR) (!)(#) **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Atraumatic Low Back Pain (QCDR) (!)(#) **ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (QCDR) (!)(#) **ECPR55:** Avoidance of Long-Acting (LA) or Extended-Release (ER) Opiate Prescriptions and Opiate Prescriptions for Greater Than 3 Days Duration for Acute Pain (QCDR)	**IA_BE_4:** Engagement of patients through implementation of improvements in patient portal (Medium) (*) **IA_BE_6:** Collection and follow-up on patient experience and satisfaction data on beneficiary engagement (High) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) (*)(~) **IA_CC_14:** Practice improvements that engage community resources to support patient health goals (Medium) **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) (*) **IA_PSPA_6:** Consultation of the Prescription Drug Monitoring Program (High) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_15:** Implementation of Antimicrobial Stewardship Program (ASP) (Medium) **IA_PSPA_19:** Implementation of formal quality improvement methods, practice changes or other practice improvement processes (Medium) **IA_PSPA_20:** Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) **Q479:** Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) (^)(!!) **TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting**	

	Clinical Data Registry Reporting **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

Table F: Proposed Improving Care for Lower Extremity Joint Repair MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Arthritis and lower extremity (LE) fracture can be costly conditions and lead to increased pain and decreased functional ability. Osteoarthritis, hip, and lower extremity fractures have been identified within the top 20 most expensive conditions for hospital costs; 19,906 million, 5,628 million and 4,368 million in 2017 respectively.[282] The proposed Improving Care for Lower Extremity Joint Repair MVP focuses on the clinical theme of providing fundamental treatment and management of patients with osteoarthritis and lower extremity surgical repair, such as fracture and total joint replacement, to ensure appropriate care and reduce costs. This MVP would be most applicable to clinicians who treat clinically varied patient types and who may also be assessed for, or who have undergone, lower extremity surgical repair, including pre- and post-operatively.

Quality Measures

Within the quality component of this MVP, we propose to include six MIPS quality measures, which promote assessment and treatment of care for patients with lower extremity orthopedic conditions, with emphasis on osteoarthritis and total joint repair/replacement. We have reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in treating patients with osteoarthritis and LE joint repair. We decided to keep the focus on total hip and knee replacement because these procedures are directly applicable to the Medicare patient population. Therefore, the following measures are proposed:

- Q350: Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy: This MIPS quality measure promotes care for non-surgical patients diagnosed with osteoarthritis with the potential to reduce overall healthcare costs associated with this chronic condition.
- Q351: Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation: This MIPS quality measure promotes appropriate pre-operative evaluation for potential venous and cardiovascular complications and to help minimize surgical risk for patients undergoing a total joint repair.
- Q376: Functional Status Assessment for Total Hip Replacement: This MIPS quality measure is a patient-reported outcome measure, that addresses functional status assessment and improvement in patients that undergo a total hip replacement.
- Q470: Functional Status After Primary Total Knee Replacement: This MIPS quality measure is a patient-reported outcome measure, that addresses functional status assessment and improvement in patients that undergo a total knee replacement.
- Q480: Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System: This MIPS quality measure is an administrative claims outcome measure that addresses lower extremity total joint surgery complications rates. As an administrative claims measure, there is no additional burden on the clinician for reporting.

In conjunction with the aforementioned lower extremity joint repair specific measures, we propose to include the following broadly applicable MIPS quality measure that are relevant to care provided by orthopedic clinicians:

- Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure addresses the assessment of body mass index (BMI) and maintenance of a healthy body weight. Specifically, it supports surgical or non-surgical patients diagnosed with osteoarthritis with potential to reduce overall healthcare costs and surgical risk associated with this chronic condition.

The following quality measures were considered for this proposed MVP but not included based on the rationales below:

- CCOME6: Patient-Reported Pain and/or Function Improvement after APM Surgery and CCOME7: Patient-Reported Pain and/or Function Improvement after Total Hip Arthroplasty were considered; however, although these QCDR measures are robust outcome measures and would be applicable to orthopedic surgeons, testing requirements will not be completed in time to include within the MVP.
- Q217: Functional Status Change for Patients with Knee Impairments and Q218: Functional Status Change for Patients with Hip Impairments were considered; however, these MIPS quality measures are more appropriate for clinicians providing rehabilitative services (i.e., physical therapy and occupational therapy).
- Q024: Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older was considered; however, to allow for clinician choice in measure selection and to capture those patients who may need osteopathic care for fractures that may not require surgery.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include 11 improvement activities that reflect actions and processes undertaken by clinicians focused on interventional strategies for the improvement of lower extremity joint repair. We have reviewed the MIPS improvement activity inventory and believe the improvement activities proposed within this MVP provide an opportunity for meaningful improvement and patient engagement for clinicians who specialize in treating patients with osteoarthritis and LE joint problems. Therefore, the following improvement activities are proposed for inclusion within this MVP:

- IA_CC_15: PSH Care Coordination: Contributes to the coordinated care of the patient required after a procedure such as a hip/knee replacement. The Perioperative Surgical Home (PSH) strives to provide the patient with the "right care, in the right place, at the right time" to ensure patient satisfaction while reducing complications and costs.
- IA_PSPA_27: Invasive Procedure or Surgery Anticoagulation Medication Management: To address blood-clotting issues commonly associated with hip/knee replacement. Statistical data indicates that hip and knee replacements are a

[282] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main, https://www.hcup-us.ahrq.gov/reports/statbriefs/sb261-Most-Expensive-Hospital-Conditions-2017.jsp.

commonly performed inpatient procedure with long recovery times that often incur sizable expenses in terms of hospitalization and rehabilitation.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care for patients experiencing LE joint problems:

- IA_AHE_3: Promote use of Patient-Reported Outcome Tools
- IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement
- IA_BE_12: Use evidence-based decision aids to support shared decision-making
- IA_CC_7: Regular training in care coordination
- IA_CC_9: Implementation of practices/processes for developing regular individual care plans
- IA_CC_13: Practice improvements for bilateral exchange of patient information
- IA_PSPA_6: Consultation of the Prescription Drug Monitoring Program
- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements
- IA_PSPA_18: Measurement and improvement at the practice and panel level

Cost Measures

Within the cost component of this MVP, we propose the Elective Primary Hip Arthroplasty and Knee Arthroplasty episode-based measures because they evaluate the costs of care for clinicians performing elective hip arthroplasty and knee arthroplasty procedures. These two episode-based measures are closely linked to the quality measures within this MVP and help provide a holistic evaluation of the value of care for elective lower extremity joint repair. The TPCC measure was considered but not included in this MVP because the TPCC cost measure focuses on primary care and ongoing clinician-patient relationships, which is not the nature of orthopedic surgery care; in addition, the orthopedic surgery specialty is excluded from the TPCC measure attribution. We considered including the MSPB Clinician measure, but ultimately did not include it as it encompasses all inpatient care, rather than focusing on the specific costs related to lower extremity joint repair.

TABLE F: Proposed Improving Care for Lower Extremity Joint Repair MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Improving Care for Lower Extremity Joint Repair MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(*) Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications) **(*)(!) Q350:** Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (MIPS CQMs Specifications) **(*)(!) Q351:** Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (MIPS CQMs Specifications) **(*)(!) Q376:** Functional Status Assessment for Total Hip Replacement (eCQM Specifications) **(*)(!!) Q470:** Functional Status After Primary Total Knee Replacement (MIPS CQMs Specifications) **(!!) Q480:** Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (Administrative Claims)	(~) **IA_AHE_3:** Promote use of Patient-Reported Outcome Tools (High) **(*) IA_BE_6:** Collection and follow-up on patient experience and satisfaction data on beneficiary engagement (High) **IA_BE_12** Use evidence-based decision aids to support shared decision-making (Medium) **IA_CC_7:** Regular training in care coordination (Medium) (~) **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans (Medium) **IA_CC_13:** Practice improvements for bilateral exchange of patient information (Medium) **(*) IA_CC_15:** PSH Care Coordination (Medium) **(*) IA_PSPA_6:** Consultation of the Prescription Drug Monitoring Program (High) (~) **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **(*) IA_PSPA_18:** Measurement and improvement at the practice and panel level (Medium) **IA_PSPA_27:** Invasive Procedure or Surgery Anticoagulation Medication Management (Medium)	**Elective Primary Hip Arthroplasty** **Knee Arthroplasty**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) (^)**(!!) TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting** **Public Health Registry Reporting**	

	Clinical Data Registry Reporting **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

Table G: Proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

Clinicians within the profession of anesthesiology evaluate, monitor, and deliver patient care before, during, and after surgeries and/or procedures to ensure optimal patient outcomes. We believe that as the population ages, and the need for surgery and interventional procedures steadily increases, the anesthesiologist can play a significant role in delivering cost-effective health care without affecting the quality of care being delivered. Relative to overall disease healthcare burden, a total of 28%-32% of global disease comes from surgical diseases.[283] The proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP focuses on increasing quality of anesthesia care, improving postoperative outcomes, promoting patient safety, and enhancing satisfaction for patients receiving anesthesia. The measures are used for a variety of surgical procedures that anesthesiologists deliver care for, and are broadly applicable to anesthesiologists practicing within ambulatory, outpatient, and inpatient hospital settings. This MVP would be most applicable to clinicians who provide anesthesia services to patients within the surgical setting or who are considered anesthesiologists or other qualified anesthesia professionals.

Quality Measures

Within the quality component of this MVP, we propose to include five MIPS quality measures and three QCDR measures, which intend to drive the quality of care within an anesthesia episode and is based on guidelines that lead to better patient outcomes for both the adult and pediatric patient populations. The anesthesiology-related quality measures are inclusive of all phases of anesthesia care: pre, intra and postoperative, including coordination with the anesthesiologist's surgical colleagues. We reviewed the MIPS quality measure inventory and believe the following quality measures proposed within this MVP provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in providing anesthesia services:

- Q404: Anesthesiology Smoking Abstinence: This MIPS quality measure uses targeted interventions to encourage smoking cessation, which can be critically important in reducing surgical risks and preventing infection, ultimately leading to faster patient recovery and reduced costs. Smoking is a precursor to multiple health challenges including respiratory and cardiovascular diseases which may interfere with metabolic processes such as oxygen delivery and uptake and drug metabolism.
- Q424: Perioperative Temperature Management: This MIPS quality measure ensures the maintenance of normothermia during surgery. Perioperative hypothermia is known to be a common occurrence with anesthesia, which can result in fluctuations in body temperature causing adverse effects on physiological functioning. This is a key clinical action under the control of the anesthesiologist that can directly lead to reduced surgical site infections, faster recovery, and reduced costs.
- Q430: Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy: This MIPS quality measure encourages effective prophylactic regimens to be used by the anesthesiologist to reduce this highly dissatisfying side effect of anesthesia. Nausea and vomiting are common side effects following anesthesia that can cause electrolyte imbalance, dehydration, aspiration, and/or slow wound healing. Decreasing occurrence of side effects can shorten recovery times, reduce costs and resources.
- Q463: Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics): This MIPS quality measure encourages effective prophylactic regimens to be used by the anesthesiologist to reduce this highly dissatisfying side effect of anesthesia. A pediatric-specific measure is needed because the risk factors and recommended prophylaxis are different from the adult population.
- Q477: Multimodal Pain Management: This patient-centered MIPS quality measure assesses the effective peri- and postoperative pain management through the utilization of multimodal pain management. Optimal perioperative pain management improves patients' function and rehabilitation after surgery. Additionally, this measure dissuades the use of opioids, which not only work primarily through a single mechanism, but can lead to a host of side effects that can be life threatening or lead to opioid abuse.

In conjunction with the MIPS quality measures specific to anesthesia, we propose to include the following QCDR measures that are relevant to reducing operative infection and incorporating the patient voice.

- AQI48: Patient-Reported Experience with Anesthesia: This QCDR measure uses patient voice to assess a patient's overall experience with anesthesia care helping to better understand the patient's satisfaction and experience.
- AQI69: Intraoperative Antibiotic Redosing: This QCDR measure addresses the importance of infection prevention by encouraging adequate and timely redosing of intraoperative antibiotics.
- AQI70: Prevention of Arterial Line Infection: This QCDR measure addresses the appropriate use of sterile techniques which are essential to prevent costly and dangerous infections.

This MVP supports the vital practice of anesthesia care in protecting patient safety and mitigating patient risk. Reducing the risk of infection, pain management, post-operative management of nausea and vomiting, as well as patient and family engagement and satisfaction can all lead to the overall goal of better outcomes for patients undergoing surgery.

Improvement Activities

Within the improvement activities component of this MVP, we propose to include 11 improvement activities that reflect actions and processes undertaken by anesthesiologists to identify interventional strategies to promote positive patient experiences with anesthesia. We have reviewed the MIPS improvement activity inventory and believe the improvement activities proposed within this MVP provide an opportunity for meaningful improvement regarding complications associated with anesthesia, which may

[283] Karim HMR. Healthcare delivery cost and anesthesiologists: Time to have a greater role and responsibility. World J Anesthesiol 2019; 8(3): 19-24.

include postoperative vomiting (POV), cardiovascular collapse, and respiratory depression. Therefore, the following improvement activities are proposed for inclusion in this MVP:

- IA_PSPA_7: Use of QCDR data for ongoing practice assessment and improvements: Promotes follow-up systems, tools, and/or strategies that could address complications often encountered after anesthesia.
- IA_PSPA_20: Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes: Promotes follow-up systems, tools, and/or strategies that could address complications often encountered after anesthesia.

Additional improvement activities are included to offer clinician choice and to promote patient engagement and patient-centeredness, health equity, shared decision making, and care coordination. These improvement activities provide additional opportunities for clinicians to drive outcomes and improve quality of care for patients receiving anesthesia:

- IA_BE_6: Collection and follow-up on patient experience and satisfaction data on beneficiary engagement
- IA_BE_22: Improved practices that engage patients pre-visit
- IA_BMH_2: Tobacco use
- IA_CC_2: Implementation of improvements that contribute to more timely communication of test results
- IA_CC_15: PSH Care Coordination
- IA_CC_19: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- IA_EPA_1: Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record
- IA_PSPA_1: Participation in an AHRQ-listed patient safety organization
- IA_PSPA_16: Use of decision support and standardized treatment protocols

Cost Measures

Within the cost component of this MVP, we propose the MSPB Clinician measure because it focuses on clinicians providing inpatient care and applies to a small subset of anesthesiologists. The TPCC measure was considered but not included in this MVP because this cost measure focuses on primary care and ongoing clinician -patient relationships, which is not the nature of anesthesiology care; in addition, the anesthesiology specialty is excluded from the TPCC measure attribution. Currently, there are no applicable episode-based measures available, but one could be considered for development in the future. Refer to section IV.A.3.d.(2) of this proposed rule for details on the current cost measure development process and potential cost measure development process that could lead to an episode-based measures related to this MVP.

TABLE G: Proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP Beginning with the CY 2023 MIPS Performance Period/2025 MIPS Payment Year

As noted in the introduction of this appendix, we considered measures and improvement activities available within the MIPS inventory and selected those that we determined best fit the clinical concept of the proposed Patient Safety and Support of Positive Experiences with Anesthesia MVP. We request comment on the measures and activities included in this MVP.

Quality	Improvement Activities	Cost
(!!) Q404: Anesthesiology Smoking Abstinence (MIPS CQMs Specifications) **(!!) Q424:** Perioperative Temperature Management (MIPS CQMs Specifications) **(*)(!) Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy (MIPS CQMs Specifications) **(*)(!) Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics) (MIPS CQMs Specifications) **(!) Q477:** Multimodal Pain Management (MIPS CQMs Specifications) **(!!)(#) AQI48:** Patient-Reported Experience with Anesthesia (QCDR) **(!)(#) AQI69:** Intraoperative Antibiotic Redosing (QCDR) **(!)(#) AQI70:** Prevention of Arterial Line-related Bloodstream Infections (QCDR)	**(*) IA_BE_6:** Collection and follow-up on patient experience and satisfaction data on beneficiary engagement (High) **IA_BE_22:** Improved practices that engage patients pre-visit (Medium) **IA_BMH_2:** Tobacco use (Medium) **IA_CC_2:** Implementation of improvements that contribute to more timely communication of test results (Medium) **(*) IA_CC_15:** PSH Care Coordination (Medium) **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes (High) **(*)(~) IA_EPA_1:** Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Records (High) **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization (Medium) **(~) IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements (Medium) **IA_PSPA_16:** Use of decision support and standardized treatment protocols (Medium) **IA_PSPA_20:** Leadership engagement in regular guidance and demonstrated commitment for implementing practice improvement changes (Medium)	**Medicare Spending Per Beneficiary (MSPB) Clinician**
Foundational Layer		
Population Health Measures	**Promoting Interoperability**	
(!!) Q479: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups (Administrative Claims) **(^)(!!) TBD:** Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Administrative Claims)	**Prevention of Information Blocking** **e-Prescribing** **Query of the Prescription Drug Monitoring Program (PDMP) (Optional)** **Provide Patients Electronic Access to Their Health Information** **Support Electronic Referral Loops By Sending Health Information** **Support Electronic Referral Loops By Receiving and Reconciling Health Information** **Health Information Exchange (HIE) Bi-Directional Exchange** **Immunization Registry Reporting** **Syndromic Surveillance Reporting** **Electronic Case Reporting**	

	Public Health Registry Reporting **Clinical Data Registry Reporting** **Security Risk Analysis** **(^) Safety Assurance Factors for EHR Resilience Guide (SAFER Guide)**

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1, 53, 54, et al.
Electronic-Filing Requirements for Specified Returns and Other Documents; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 53, 54 and 301

[REG–102951–16]

RIN 1545–BN36

Electronic-Filing Requirements for Specified Returns and Other Documents

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking; notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations amending the rules for filing electronically and affects persons required to file partnership returns, corporate income tax returns, unrelated business income tax returns, withholding tax returns, and certain information returns, registration statements, disclosure statements, notifications, actuarial reports, and certain excise tax returns. The proposed amendments reflect changes made by the Taxpayer First Act of 2019 (TFA) and are consistent with the TFA's emphasis on increasing electronic filing. This document also withdraws proposed regulations published in the **Federal Register** on May 31, 2018, amending the rules for determining whether information returns must be filed electronically.

DATES: Written or electronic comments must be received by September 21, 2021. The public hearing is being held by teleconference on September 22, 2021 at 10 a.m. EST. Requests to speak and outlines of topics to be discussed at the public hearing must be received by September 21, 2021. If no outlines are received by September 21, 2021, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5:00 p.m. EST on September 20, 2021. The telephonic hearing will be made accessible to people with disabilities. Requests for special assistance during the telephonic hearing must be received by September 20, 2021.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–102951–16) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to its public docket. Send paper submissions to: CC:PA:LPD:PR (REG–102951–16), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, call Casey R. Conrad of the Office of the Associate Chief Counsel (Procedure and Administration), (202) 317–6844; concerning submission of comments or requests for a public hearing, call Regina Johnson, (202) 317–5177 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Regulations on Income Taxes (26 CFR part 1) under sections 1461 and 1474 of the Internal Revenue Code (Code), which provide that persons required to deduct and withhold tax are liable for such tax, and section 6050I of the Code, which requires persons to report information about financial transactions to the IRS; to the Regulations on Pension Excise Taxes (26 CFR part 54) under section 6011 of the Code, which requires persons to report information for certain excise taxes related to employee benefit plans; to the Regulations on Procedure and Administration (26 CFR part 301) under sections 1474, 6011, 6012, 6033, 6057, 6058, and 6059 of the Code for determining whether returns must be filed using magnetic media; and to the Regulations on Foundation and Similar Excise Taxes (26 CFR part 53) under section 6011 of the Code to remove the option—available to a person required to report certain excise taxes on Form 4720, *Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code*—to designate a Form 4720 filed by a private foundation or trust as that person's return if the foundation is reporting the same transaction. This document also withdraws proposed regulations under section 6011 that were published in the **Federal Register** on May 31, 2018 (May 2018 proposed regulations), amending the rules for determining whether information returns must be filed using magnetic media.

Section 6011(e) was added to the Code by section 319 of the Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248, 96 Stat. 610, and required the Secretary of the Treasury or her delegate (Secretary) to prescribe regulations providing standards for determining which returns were required to be filed on magnetic media (hereinafter references to filing ''in electronic form'' will be used in place of filing ''on magnetic media''). A year later, the statute was amended by section 109 of the Interest and Dividend Tax Compliance Act of 1983, Public Law 98–67, 97 Stat. 383, to require information returns under sections 6042(a) (dividends and corporate earnings and profits), 6044(a) (patronage dividends), and 6049(a) (interest), with respect to more than 50 payees for any calendar year, to be filed electronically. The amendment also added a waiver provision from electronically filing to any person who established undue hardship.

On March 25, 1986, the Secretary first published guidance under section 6011(e) with respect to the electronic filing requirement as § 301.6011–2 (TD 8081), which specified Forms 1042–S, 1098, 1099 series, 5498, 6248, 8027, W–2G, W–2, W–2P as the information returns covered by the regulation that had to be filed electronically unless the person was granted a waiver or was a low-volume filer. The term ''low-volume filers'' was defined as persons not required to file, for any calendar year beginning on or after January 1, 1987, 250 or more of the specified returns (other than Forms 1099–DIV, *Dividends and Distributions;* 1099–PATR, *Taxable Distributions Received from Cooperatives;* 1099–INT, *Interest Income;* or 1099–OID, *Original Issue Discount*). For those four Forms 1099, the regulation provided a special rule that reduced the 250-return threshold to 50 and required that the four forms be aggregated for purposes of determining whether a person met the 50-return threshold. The regulation also provided that the Commissioner of Internal Revenue or his delegate (Commissioner) could prescribe by revenue procedure additional forms to be covered by the regulation.

Section 6011(e) was again amended in 1989 by section 7713, Title VII, of the Revenue Reconciliation Act of 1989 (1989 Act), Public Law 101–239, 103 Stat. 2394, to prohibit the Secretary from requiring any person to file returns electronically unless that person was required to file at least 250 returns during the calendar year. The 1989 Act also required the Secretary to consider the taxpayer's ability to comply at reasonable costs with the regulation's requirements.

On June 30, 1998, the Secretary promulgated amending regulations under section 6011(e), § 301.6011–2 (TD 8772), that removed the special rules related to the four Forms 1099 and

clarified that the 250-return threshold applied separately to each information return covered by § 301.6011–2. The regulation also added Forms 499R–2/W–2PR, W–2VI, W–2GU, and W–2AS as information returns covered by the regulation and removed Form 6248.

On August 5, 1997, the President signed into law the Taxpayer Relief Act of 1997, Public Law 105–34. Section 1224 of that Act amended 6011(e)(2) by adding a sentence that required the Secretary to promulgate regulations to require partnerships with over 100 partners to file returns electronically. On November 12, 1999, the Secretary promulgated regulations under section 6011(e) relating to this special rule for partnerships with more than 100 partners, § 301.6011–3 (TD 8843), requiring partnerships with more than 100 partners to file partnership returns and all information required by the applicable forms and schedules electronically.

On April 29, 2002, the Secretary promulgated regulations under section 6011(e) (TD 8992) to add Form 1098–E as an information return covered by the regulation; on February 7, 2003, the Secretary promulgated regulations under section 6011(e) (TD 9029) to add Form 1098–T as an information return covered by the regulation.

On November 13, 2007, the Secretary promulgated regulations relating to the requirements for filing corporate income tax returns and returns of organizations required to file returns under section 6033 electronically under section 6011(e), § 301.6011–5, § 301.6033–4, and § 301.6037–2 (TD 9363). The regulations specify that all returns required to be filed during the calendar year, including income tax returns, employment tax returns, excise tax returns, and information returns, are counted in determining whether a corporation or organization meets the 250-return threshold. Sections 301.6011–5 and 301.6037–2 apply to large corporations and S corporations, respectively, if the corporation is required to file at least 250 returns during the calendar year and the corporation reports total assets at the end of the corporation's taxable year that equal or exceed $10 million on Schedule L of their Form 1120 ($10 million rule). Section 301.6033–4 applies to organizations required to file Form 990, *Return of Organization Exempt From Income Tax,* that have total assets of $10 million or more as of the end of the taxable year, and that are required to file at least 250 returns during the calendar year; it also applies to any organization (regardless of total assets) required to file Form 990–PF, *Return of Private Foundation or Section 4947(a)(1) Trust Treated as Private Foundation,* if the organization is required to file at least 250 returns during the calendar year.

Section 6011(e)(4) was added to the Code in 2010 by section 522, Title V, of the Hiring Incentives to Restore Employment (HIRE) Act, Public Law 111–147, 124 Stat. 71, to authorize the Secretary to require financial institutions that file returns with respect to withholding on foreign transfers to file those returns electronically regardless of the number. On January 28, 2013, the Secretary promulgated regulations under section 1474(f), § 301.1474–1 (TD 9610), to require financial institutions defined in section 1471(d)(5) to electronically file Form 1042–S, *Foreign Persons' U.S. Source Income Subject to Withholding,* regardless of the number of returns filed for the calendar year, but did not include in those regulations a requirement to electronically file Form 1042, *Annual Withholding Tax Return for U.S. Source Income of Foreign Persons*.

On March 10, 2014, the Secretary promulgated regulations under section 6011(e), § 301.6011–2 (TD 9660), to add the Forms 1094 series and 1095 series as information returns covered by the regulation. And on December 19, 2016, the Secretary promulgated regulations under section 6011(e), § 301.6011–2 (TD 9804), to remove the Form 1095 series and add Form 1095–B and Form 1095–C as information returns covered by the regulation.

On March 23, 2018, the President signed into law the Tax Technical Corrections Act of 2018 (TTCA), Public Law 115–141. Section 301, div. U, title III, of the TTCA added a new paragraph (5), Special rule for partnerships, to section 6011(e). Section 6011(e)(5)(A), Partnerships permitted to be required to file on magnetic media, authorized the Secretary to lower the electronic-filing threshold to 200 returns and statements for all partnerships filing returns and statements relating to calendar year 2018, reducing that number by 50 each year until 2023, when partnerships filing more than 20 returns and statements relating to 2022 or any subsequent calendar year could be required to file electronically. The TTCA also moved the rule authorizing the Secretary to require partnerships with more than 100 partners to file their returns electronically from section 6011(e)(2) to new section 6011(e)(5)(B), Partnerships required to file on magnetic media. The Secretary did not promulgate regulations under section 6011(e) relating to the lower electronic-filing thresholds for partnerships.

On May 31, 2018, the Secretary proposed regulations under section 6011(e) (83 FR 24948) amending § 301.6011–2. The proposed regulations would have required that all information returns covered under that regulation, regardless of type, be included in determining whether the returns a person must file meet the 250-return threshold and the person must file the information returns electronically. The May 2018 proposed regulations also provided that corrected information returns would be required to be filed electronically if the corresponding original return was required to be filed electronically.

On July 1, 2019, the President signed into law the Taxpayer First Act of 2019 (TFA), Public Law 116–25. Section 2301 of the TFA amended section 6011(e) by adding new paragraph 5 that authorizes the Secretary to prescribe regulations that decrease, in accordance with the TFA, the number of returns a taxpayer may file without being required to file electronically. These amendments included changes to the special rule for partnerships. Section 2301 of the TFA moved the rule requiring partnerships with more than 100 partners to file returns electronically from section 6011(e)(5), titled ''Partnerships required to file on magnetic media'', to new section 6011(e)(6). Section 3101 of the TFA amended section 6011 to require any charitable or other organization required to file an annual return that relates to any tax imposed by section 511 on unrelated business taxable income to file those returns in electronic form. Section 3101 of the TFA also amended section 6033 to require any organization required to file a return under section 6033 to file those returns in electronic form.

On November 19, 2020, the Secretary promulgated regulations under section 529A of the Code, which amended a regulation under section 6011(e) of the Code, § 301.6011–2 (TD 9923), to add the Forms 5498–ESA, *Coverdell ESA Contribution Information,* 5498–QA, *ABLE Account Contribution Information,* and 5498–SA, *HSA, Archer MSA, or Medicare Advantage MSA Information,* as information returns covered by the regulation.

On December 20, 2019, the President signed into law the Setting Every Community Up for Retirement Enhancement Act of 2019 (SECURE Act), enacted as part of the Further Consolidated Appropriations Act, 2020, Public Law 116–94, div. O. Section 202 of the SECURE Act allows a group of plans to file a single aggregated annual

return or report for plan years beginning after December 31, 2021. Section 202(d) of the SECURE Act clarifies the electronic-filing requirements for these deferred compensation plans. Section 202 of the SECURE Act also added to section 6011 a second paragraph (e)(6), although the headings of the two paragraphs (e)(6) differ. The one moved to paragraph (e)(6) by the TFA is titled ''Partnerships required to file on magnetic media.'' The one added by the SECURE Act is titled ''Application of numerical limitation to returns related to deferred compensation plans'' and treats information regarding each plan for which information is provided on a return required to be filed under section 6058 of the Code as a separate return for purposes of determining the number of returns a taxpayer may file without being required to file electronically. These proposed regulations do not address amendments made by section 202(d) of the SECURE Act.

Explanation of Provisions

1. Scope of the Proposed Regulations for Filing Returns Electronically

These proposed regulations would impose electronic-filing requirements on persons required to file certain returns as authorized by the TFA by amending the following regulations:

(1) § 301.6011–2, Required use of electronic form, which prescribes standards for determining whether certain information returns must be filed electronically;

(2) § 1.6045–2, Furnishing statement required with respect to certain substitute payments, which requires persons to report certain substitute payments;

(3) § 1.6045–4, Information reporting on real estate transactions with dates of closing on or after January 1, 1991, which requires persons to report on real estate transactions;

(4) § 1.6050I–0, Table of contents, which lists the major captions that appear in §§ 1.6050I–1 and 1.6050I–2;

(5) § 1.6050I–1, Returns relating to cash in excess of $10,000 received in a trade or business, which requires persons to report information about these financial transactions to the IRS;

(6) § 1.6050I–2, Returns relating to cash in excess of $10,000 received as bail by court clerks, which requires persons to report information about these financial transactions to the IRS;

(7) § 1.6050M–1, Information returns relating to persons receiving contracts from certain Federal executive agencies, which requires certain Federal executive agencies to report information with respect to each contract entered into by that agency;

(8) § 301.6721–1, Failure to file correct information returns, which provides the penalty for failure to file correct information returns;

(9) § 301.6011–3, Required use of electronic form for partnership returns, which prescribes standards for determining whether a partnership must file its partnership return electronically;

(10) § 301.6011–5, Required use of electronic form for corporate income tax returns, which prescribes standards for determining whether a corporation must file its corporate income tax returns electronically;

(11) § 1.6037–2, Required use of electronic form for income tax returns of electing small business corporations, which prescribes standards for determining whether an electing small-business corporation (S corporation) must file its S corporation return electronically;

(12) § 301.6037–2, Required use of electronic form for returns of electing small business corporations, which prescribes standards for determining whether an electing small-business corporation (S corporation) must file its S corporation return electronically;

(13) § 1.6033–4, Required filing in electronic form for returns by organizations required to file returns under section 6033, which prescribes standards for filing returns required to be filed electronically under § 301.6033–4;

(14) § 301.6033–4, Required filing in electronic form for returns by organizations required to file returns under section 6033, which prescribes standards for determining whether returns by organizations required to file a return under section 6033 must be filed electronically;

(15) § 53.6011–1, General requirement of return, statement or list, which requires persons subject to certain enumerated excise taxes under Chapter 42 of the Code to file a Form 4720 to accompany payment of those excise taxes;

(16) § 301.6057–3, Required use of electronic form for filing requirements relating to deferred vested retirement benefit, which prescribes standards for determining whether a registration statement required to be filed under section 6057(a) or a notification required to be filed under section 6057(b) must be filed electronically;

(17) § 301.6058–2, Required use of electronic form for filing requirements relating to information required in connection with certain plans of deferred compensation, which prescribes standards for determining whether a return required to be filed under section 6058 with respect to an employee benefit plan must be filed electronically; and

(18) § 301.6059–2, Required use of electronic form for filing requirements relating to periodic report of actuary, which prescribes standards for determining whether an actuarial report required to be filed under section 6059 with respect to an employee benefit plan must be filed electronically.

The proposed regulations would also create the following new regulations that impose an electronic-filing requirement:

(1) § 301.6011–10, Certain organizations, including trusts, required to file unrelated business income tax returns in electronic form, which requires certain organizations, including trusts, to file their unrelated business income tax returns electronically;

(2) § 301.6011–11, Required use of electronic form for certain returns for tax-advantaged bonds, which prescribes standards for determining whether a return for credit payments to issuers of qualified bonds must be filed electronically;

(3) § 301.6011–12, Required use of electronic form for returns of certain excise taxes under chapters 41 and 42 of the Internal Revenue Code, which prescribes standards for determining whether an excise tax return on Form 4720 must be filed electronically;

(4) § 301.6011–13, Required use of electronic form for split-interest trust returns, which prescribes standards for determining whether an information return on Form 5227 must be filed electronically;

(5) § 301.6011–14, Required use of electronic form or other machine-readable form for material advisor disclosure statements, which prescribes standards for determining whether a material advisor disclosure statement on Form 8918 must be filed electronically or in other machine-readable form;

(6) § 301.6012–2, Required use of electronic form for income tax returns of certain political organizations, which prescribes standards for determining whether an income tax return on Form 1120–POL must be filed electronically;

(7) § 54.6011–3, Required use of electronic form for the filing requirements for the return for certain excise taxes related to employee benefit plans, which prescribes standards for determining whether an income tax return on Form 5330, *Return of Excise Taxes Related to Employee Benefit Plans,* must be filed electronically; and

(8) § 301.6011–15, Required use of electronic form for withholding tax returns, which prescribes standards for determining whether an income tax

return filed by a withholding agent on Form 1042 must be filed electronically.

In addition, the proposed regulations would amend the following regulations regarding the filing requirements of withholding agents:

(1) § 1.1461–1, Payment and returns of tax withheld, which prescribes requirements for withholding agents to file returns with respect to U.S. source income of foreign persons;

(2) § 1.1471–0, Outline of regulation provisions for sections 1471 through 1474, which lists the major captions that appear in §§ 1.1471–1 through 1.1474–7 and § 301.1474–1;

(3) § 1.1474–1, Liability for withheld tax and withholding agent reporting, which provides rules for withholding agents making payments under chapters 3 or 4 of the Code; and

(4) § 301.1474–1, Required use of electronic form for financial institutions filing Form 1042–S or Form 8966, which provides rules for withholding agents making payments under chapter 4 of the Code.

The regulations proposed in this document include reordering and renumbering of paragraphs when necessary for clarification and logic. In addition, cross references have been updated, and typographical, grammatical, and punctuation corrections have been made.

As many of these regulations imposing electronic-filing requirements also provide a waiver from electronically filing to any person who establishes undue hardship, the Treasury Department and the IRS request comments on how the hardship waiver procedures should be administered, including suggestions for revising the procedures for requesting, and criteria for granting, a hardship waiver.

2. Proposed § 301.6011–2, Rules for Filing Certain Information Returns Electronically

These proposed regulations would amend § 301.6011–2 as discussed in detail in the following sections 2.A though 2.G.

A. Additional Information Returns Required To Be Filed Electronically

i. Forms 1098–C and 1098–Q

Section 301.6011–2(b)(1) provides a list of information returns required to be filed electronically in accordance with § 301.6011–2. Among those returns are three in the Form 1098 series: Form 1098, *Mortgage Interest Statement;* Form 1098–E, *Student Loan Interest Statement;* and Form 1098–T, *Tuition Statement,* added to § 301.6011–2(b)(1) by, respectively, TD 8081 (March 25, 1986), TD 8992 (April 29, 2002), and TD 9029 (February 7, 2003). After those three forms were added to § 301.6011–2(b)(1), the IRS created additional returns in the Form 1098 series: Form 1098–C, *Contributions of Motor Vehicles, Boats, and Airplanes*; and Form 1098–Q, *Qualifying Longevity Annuity Contract Information.* These two additional 1098 series forms, as well as the three currently listed in § 301.6011–2(b), are all filed and furnished by larger organizations and institutions that generally electronically file returns even when not required to do so by § 301.6011–2. Based on the size and sophistication of the entities that file these forms and the accessibility and availability of electronic filing, the Treasury Department and the IRS have determined that filers of Forms 1098–C and 1098–Q are unlikely to incur unreasonable costs to electronically file these returns. Thus, the proposed regulations would amend § 301.6011–2(b)(1) to add Forms 1098–C and 1098–Q to the list of information returns covered by § 301.6011–2(b).

ii. Forms 3921 and 3922

The proposed regulations would also amend § 301.6011–2(b)(1) to add the Form 3921, *Exercise of an Incentive Stock Option Under Section 422(b),* and Form 3922, *Transfer of Stock Acquired Through an Employee Stock Purchase Plan Under Section 423(c).* These forms are filed and furnished by sophisticated taxpayers that generally electronically file returns even when not required to do so by § 301.6011–2. Based on the sophistication of these filers and the accessibility and availability of electronic filing, the Treasury Department and the IRS have determined that filers of Forms 3921 and 3922 are unlikely to incur unreasonable costs to electronically file these returns.

iii. Form 1097–BTC

The proposed regulations would also amend § 301.6011–2(b)(1) to add the Form 1097–BTC, *Bond Tax Credit.* This form is filed and furnished by bond issuers with respect to certain tax credit bonds. For the reasons discussed in this preamble, the Treasury Department and the IRS have determined that filers of Form 1097–BTC should not incur any unreasonable costs to electronically file this return. See section 2.D., Aggregation of returns to determine whether the electronic-filing threshold is met. Proposed § 301.6011–2 would allow for a waiver of the electronic filing requirements for Form 1097–BTC if hardship is shown in a request for waiver made in accordance with the regulation.

B. Form 8300 Required To Be Filed Electronically

Form 8300, *Report of Cash Payments Over $10,000 Received in a Trade or Business,* is a dual-purpose form, designed to meet both the section 6050I reporting requirement and, since January 1, 2002, a similar Bank Secrecy Act (BSA) reporting requirement found in 31 U.S.C. 5331 and 31 CFR 1010.330. Generally, any person in a trade or business who receives more than $10,000 in cash in a single transaction or related transactions must file Form 8300. The IRS uses the information on the Form 8300 for civil and criminal tax administration and compliance. The Financial Crimes Enforcement Network (FinCEN) relies on up-to-date Form 8300 filings for law enforcement, reporting, and statistical purposes. The instructions on Form 8300 state that filers can file the form either on paper with the IRS or electronically through FinCEN's BSA E-Filing System.

Approximately 250,000 of the 300,000 Forms 8300 filed during each calendar year from 2015 to 2018 were filed on paper with the IRS. IRS employees manually input data from the paper-filed Forms 8300 into FinCEN's BSA E-Filing System. This procedure requires significant resources to be spent on processing and data entry. Manual data entry can cause delays in the input and retrieval of data, affecting the timeliness of information available for law enforcement and other users to detect potential money laundering, terrorist financing, and other tax and financial fraud.

These proposed regulations would require filers who are required to file at least the applicable number of returns identified in paragraphs (b)(1) and (b)(2) of proposed § 301.6011–2 during the calendar year to also file their Forms 8300 electronically, as directed by the form's instructions. This requirement would increase the timeliness and accuracy of data entry, reduce postage costs, promote IT modernization efforts, reallocate IRS staff for priority assignments, and provide IRS criminal and civil investigators and other agencies with access to the data with up-to-date and accurate information. Electronic filing would also protect against possible future disruption and delays in processing paper-filed Forms 8300. It is anticipated that the form will direct filers to use FinCEN's BSA E-Filing system (*https://bsaefiling.fincen.treas.gov/main.html*), which is an internet-based secure system with no cost to the user. The only technical

requirement of the BSA E-Filing System is to have an internet connection for access to the system. Nonetheless, the proposed regulations would continue to allow the Commissioner to waive the requirement to file information returns electronically if the request for waiver demonstrates hardship. The principal factor in determining hardship will be the extent, if any, to which the cost of electronically filing Form 8300 exceeds the cost of filing Form 8300 on paper. The proposed regulations would also edit the example in § 1.6050I–1(d)(2)(iv) to provide additional clarity for the rule illustrated in that example.

C. Amending the Electronic-Filing Threshold

Under section 6011(e)(1), the Secretary must prescribe regulations providing standards for determining which returns must be filed electronically. Section 6011(e)(2)(A), however, until it was amended by the TFA, prevented the Secretary from requiring any person to file returns electronically unless the person was required to file at least 250 returns during the calendar year. Section 2301 of the TFA amended section 6011(e), changing the statutory 250-return threshold to a decreasing number over several years, as set forth in new section 6011(e)(5). In accordance with section 2301 of the TFA, these proposed regulations would amend § 301.6011–2(c)(1)(i), which currently provides that no person is required to electronically file an information return covered under § 301.6011–2(b) unless the person is required to file 250 or more returns during the calendar year. The proposed amendments would remove references to the 250-return threshold in § 301.6011–2(c)(1)(i) and add a new paragraph (c)(3)(i) to § 301.6011–2 that, in accordance with the TFA, reduces the electronic-filing threshold for information returns covered under § 301.6011–2(b) from 250 to 100, for returns required to be filed during calendar year 2022, and from 100 to 10, for returns required to be filed during calendar years after 2022.

Information returns are generally required to be filed between January and March of the year following the calendar year to which such returns relate. See sections 6071(b) and (c). If a taxpayer has, for example, 13 employees in calendar year 2022 and is required to file Forms W–2 for those employees during calendar year 2023, that taxpayer would, under these proposed regulations, be required to file those 13 Forms W–2 electronically.

The proposed incremental step-down from 250 to 100 for information returns required to be filed during calendar year 2022, and then from 100 to 10 for information returns required to be filed after 2022, will allow the IRS time to ensure it has sufficient resources and updated programming to seamlessly handle and process the increased volume of electronically-filed information returns and the applications required to file those information returns electronically.

The Treasury Department and the IRS expect that by calendar year 2023 the IRS will be prepared to handle and process the anticipated increased volume of returns and applications, and that no further incremental step-down would be necessary if these proposed regulations are finalized and applicable to returns required to be filed during calendar year 2023. Consequently, persons required to file at least 10 information returns during the calendar year 2023 would be required to file those returns electronically. The Treasury Department and the IRS request comments on why persons required to file at least 10 information returns during the calendar year 2023 would not be able to file those returns electronically during that calendar year and whether the Treasury Department and the IRS should provide an incremental step-down to 100 for information returns required to be filed during calendar year 2023, and then from 100 to 10 for information returns required to be filed during calendar years after 2023.

D. Aggregation of Returns To Determine Whether the Electronic-Filing Threshold Is Met

Section 301.6011–2(c)(1)(iii) provides that each type of information return covered under § 301.6011–2(b) is considered separately for purposes of determining whether a person meets the 250-return electronic-filing threshold. Therefore, different types of information returns are not counted in the aggregate for purposes of determining whether a person is required to file a number of returns that equals or exceeds the 250-return electronic-filing threshold during the calendar year (non-aggregation rule).

These proposed regulations would remove the non-aggregation rule from § 301.6011–2(c)(1)(iii). Section 6011(e) does not prohibit the aggregation of information returns of different types in determining whether a person meets the electronic-filing threshold during a calendar year. When the regulations specifically providing for non-aggregation were published in 1998, electronic filing was still in the early stages of development and not as commonly used as it is today. Both the 250-return limitation that Congress had included in the 1989 amendment to section 6011(e) and the non-aggregation rule that the Secretary prescribed helped ensure that electronic-filing burdens and costs were appropriate, given the existing limits and accessibility to electronic-filing technology at that time.

Since that time, electronic filing has become more common, accessible, and economical, as evidenced by the prevalence of tax-return preparers and third-party service providers who offer return-preparation and electronic-filing services, by the availability of tax-return-preparation software, and by the numbers of returns already being filed electronically on a voluntary basis. In 2018, for example, approximately 98.5 percent of information returns were filed electronically. Moreover, electronic filing increases the IRS's timeliness and accuracy in processing return information, which, in turn, provides faster and better customer service to taxpayers with respect to those returns.

In light of the prevalence of electronic filing and Congress's enactment of the TFA, which significantly expanded the Secretary's authority to prescribe regulations requiring persons to file returns electronically, the Treasury Department and the IRS have determined that the non-aggregation rule is no longer necessary and propose to remove it from § 301.6011–2(c). The proposed regulations would add a new paragraph (c)(4)(i) to § 301.6011–2 to provide that a person required to file original information returns of any type covered by § 301.6011–2(b)(1) and (b)(2) must count all those returns together to determine whether the person meets or exceeds the electronic-filing threshold for the relevant calendar year.

The proposed regulations do not include Forms 8300 in the aggregation rule, and no Form 8300 would be included in determining whether a person is required to file the applicable number of information returns. A Form 8300 generally must be filed within 15 days after a reportable payment of more than $10,000 is received. A filer may not know the number of Forms 8300 it will file in a calendar year until after the year is over, because the filer will not know how many cash transactions over $10,000 will occur during the year. On the other hand, other information returns described in § 301.6011–2(b)(1) and (2) do not need to be filed until after the calendar year of the event being reported. A filer of those other information returns will therefore know at the beginning of the calendar year whether the filer is required to file at

least the applicable number of those other information returns because those returns relate to the preceding calendar year. Thus, the Treasury Department and the IRS propose to require electronic filing of Forms 8300 only if the filer is required to file other information returns electronically.

Under these proposed regulations, filers would generally understand early in the calendar year their electronic-filing obligations for Forms 8300 without an unduly complex aggregation rule. In addition, these proposed regulations are consistent with the TFA's emphasis on development, improvement, and expansion of modern technology (see, for example, ''An Act To amend the Internal Revenue Code of 1986 to modernize and improve the Internal Revenue Service, and for other purposes'' and ''Subtitle B—Development of Information Technology'' under ''Title II—21st Century IRS''), and are within the Secretary's expanded authority under the TFA to prescribe regulations requiring persons to file returns electronically.

E. Corrected Returns Must Be Filed in the Same Manner as the Original Return

Section 301.6011–2 provides that the non-aggregation rule applies separately to each type of corrected information return covered by § 301.6011–2(b) such that, for purposes of determining whether a person meets the 250-return electronic-filing threshold, corrected information returns are counted separately from original information returns, and each type of corrected information return is counted separately.

The Treasury Department and the IRS have determined that, to increase the IRS's timeliness and accuracy in processing information returns, if persons are required to file original information returns electronically, they must file any corresponding corrected information returns electronically. Likewise, if persons permitted to file information returns on paper file those information returns on paper, they must also file any corresponding corrected information returns on paper. As discussed in the next three paragraphs, this will increase the IRS's efficiency in processing returns and should not cause taxpayers to incur unreasonable costs.

Paper information returns are generally filed at one of three different IRS Submission Processing Centers, depending on the filer's legal residence (for individuals) or principal place of business (for entities). When the IRS receives paper returns, it must convert the return to an electronic-data record before it can use the information effectively. Electronic information returns, on the other hand, do not go through Submission Processing Centers; they are generally filed through the IRS's Filing Information Returns Electronically (FIRE) system or Affordable Care Act Information Returns (AIR) system, depending on the type of return.

Because the procedures for processing electronic returns and paper returns are different, when an original return is filed on paper and a corrected return is filed electronically shortly thereafter, the IRS may not have finished processing the original paper return before the electronic return is received. The IRS is thus not able to reconcile differences as quickly as when the original and corrected returns are filed in the same manner. Similar processing issues arise when an original return is filed electronically and the corrected return is filed on paper.

This proposed requirement will not result in any additional costs or burdens on taxpayers with respect to electronic filing because a filer who filed the original return electronically has the software necessary to file a corrected return electronically. Thus, the proposed regulations would add new paragraphs (c)(4)(ii)(A) and (c)(4)(ii)(B) to § 301.6011–2 to provide that corrected information returns must be filed electronically if the corresponding original return was required to be filed electronically, and that corrected returns must be filed on paper if the corresponding original return was permitted to be, and was, filed on paper. In addition, the proposed regulations would amend § 301.6721–1(a)(2)(ii), as discussed under section 5, Proposed § 301.6721–1, Rules Relating to Penalties for Failure to File Correct Information Returns, to provide that a failure to file a corrected information return in the same manner as the corresponding original will be deemed a failure to correct the corresponding original information return.

F. Special Electronic-Filing Threshold for Partnerships of Any Size

Section 2301 of the TFA amended the special rule for partnerships in section 6011(e)(5) to authorize the Secretary to reduce the electronic-filing threshold for partnerships required to file returns. The amended special rule for partnerships authorized the Secretary to reduce the electronic-filing threshold at an accelerated rate when compared to the general electronic-filing threshold, phasing out this special rule for partnerships for returns required to be filed during calendar years after 2021. These proposed regulations do not include a special electronic-filing threshold for partnerships because the final regulations are not expected to be applicable before the 2022 filing season, at which point the special rule for partnerships will be phased out. For all the reasons discussed in this preamble, the proposed regulations would reduce, for all persons, including partnerships, the electronic-filing threshold for information returns covered under § 301.6011–2(b) from 250 to 100, for returns required to be filed during calendar year 2022, and from 100 to 10, for returns required to be filed during calendar years after 2022. See section 2.C., Amending the electronic-filing threshold.

G. Special Electronic-Filing Rule for Partnerships Having More Than 100 Partners

Paragraph (6) of section 6011(e), as that section was amended by the TFA, provides, ''Notwithstanding paragraph (2)(A), the Secretary shall require partnerships having more than 100 partners to file returns on magnetic media'' (100-partner rule). The statute uses the general term ''returns'' without specifying the type of returns that must be filed electronically. But the legislative history of the Taxpayer Relief Act of 1997, which added the 100-partner rule to section 6011(e), mentions the rule's application only with respect to partnership returns. H.R. Rep. No. 105–220, at 675 (1997) (Conf. Rep.) (''The House bill provides generally that any partnership is required to provide the tax return of the partnership (Form 1065), as well as copies of the schedule[s] sent to each partner (Form K–1), to the Internal Revenue Service on magnetic media. An exception is provided for partnerships with 100 or fewer partners.'').

In accordance with this legislative history, the Secretary promulgated regulations in 1999, § 301.6011–3 (TD 8843), requiring partnerships with more than 100 partners to file partnership returns and all other information required by the applicable forms and schedules electronically.

In 2018, however, Congress enacted the TTCA and moved this 100-partner rule from section 6011(e)(2), where it appeared as flush language under the 250-threshold limitation, to a new subparagraph (B) under section 6011(e)(5), ''Special rules for partnerships.'' There is no legislative history to the 2018 TTCA that explains why Congress moved the 100-partner rule. But after the TTCA was enacted, the Joint Committee on Taxation describes the rule with respect to ''returns,'' rather than ''tax return of the

partnership (Form 1065),'' which is how the legislative history of the Taxpayer Relief Act of 1997 described it. Staff of the J. Comm. On Taxation, Technical Explanation of the Revenue Provisions of the House Amendment to the Senate Amendment to H.R. 1625, at 52 (JCX–6–18) (''Present law requires that . . . . partnerships having more than 100 partners are required to file returns electronically.''). In 2019, a year after TTCA moved the 100-partner rule, Congress, in Title II of the TFA, under Subtitle D, ''Expanded Use of Electronic Systems,'' again moved the 100-partner rule to a new paragraph (6) under section 6011(e), ''Partnerships required to file on magnetic media.''

In light of the Joint Committee on Taxation's referring to ''returns'' in general in describing this provision of the TTCA, the TFA's emphasis on development, improvement, and expansion of modern technology, as discussed in this preamble, the TFA's emphasis on electronic filing (see ''Subtitle D—''Expanded Use of Electronic Systems'' under Title II), and the accessibility and prevalence of electronic filing, the Treasury Department and the IRS propose to add a new paragraph (c)(3)(ii)(B) to § 301.6011–2 to require partnerships with more than 100 partners to file their information returns covered by § 301.6011–2(b) electronically, regardless of the number of information returns being filed.

3. Proposed § 1.6050I–0, Table of Contents, and § 1.6050I–1, Returns Relating to Cash in Excess of $10,000 Received in a Trade or Business

Section 1.6050I–1(e)(1) provides that Form 8300 must be filed with the IRS by the 15th day after the date cash in excess of $10,000 is received in a trade or business. Section 1.6050I–1(e)(3) provides that Form 8300 must be filed by mailing it to the address shown in the instructions on the form. For all the reasons discussed in this preamble, the proposed regulations would remove references to mailing Form 8300 to the IRS and require that the form be filed as directed by the form's instructions. See section 2.B., Form 8300 required to be filed electronically; section 2.C., Amending the electronic-filing threshold; and section 2.D., Aggregation of returns to determine whether the electronic-filing threshold is met. The instructions to Form 8300 will explain how to file the form electronically. The proposed regulations would also update outdated citations in § 1.6050I–0 and § 1.6050I–1 that cross-reference to the regulations under Title 31 of the CFR and clarify the example in § 1.6050I–1(d)(2)(iv).

4. Proposed § 1.6050I–2, Returns Relating to Cash in Excess of $10,000 Received as Bail by Court Clerks

Section 1.6050I–2(c)(1)(i) provides that Form 8300 must be filed with the IRS by the 15th day after the date cash bail in excess of $10,000 is received. Section 1.6050I–2(c)(3)(i) provides that Form 8300 must be filed with the IRS office designated in the instructions on the form. For all the reasons discussed in this preamble, the proposed regulations would remove references to filing Form 8300 with a specific IRS office and require that the form be filed as directed by the form's instructions. See section 2.B., Form 8300 required to be filed electronically; section 2.C., Amending the electronic-filing threshold; and section 2.D., Aggregation of returns to determine whether the electronic-filing threshold is met. The instructions to Form 8300 will explain how to file the form electronically.

5. Proposed § 301.6721–1, Rules Relating to Penalties for Failure To File Correct Information Returns

Paragraph (a)(2)(ii) of § 301.6721–1, Failure to file correct information returns, states that no penalty will be imposed solely by reason of failing to file electronically, except to the extent that a failure occurs with respect to more than 250 returns. In accordance with changes made to the 250-return threshold by section 2301 of the TFA, the proposed amendments to § 301.6721–1 would remove references to a 250-return threshold with respect to penalties for failure to file correct information returns.

Section 301.6721–1(a)(2)(ii) also states that the threshold requirements apply separately to original and corrected returns, such that a filer that files 300 returns on Form 1099–DIV and later files 70 corrected returns on Form 1099–DIV could file the corrected returns either on the prescribed paper form (because they fall below the 250-threshold requirement) or electronically. For the reasons discussed in this preamble, the Treasury Department and the IRS propose to remove this rule because they have determined that corrected returns should be filed electronically if the corresponding original returns were so filed. See section 2.E., Corrected returns must be filed in the same manner as the original return. These proposed regulations would thus amend § 301.6721–1(a)(2)(ii) to provide that a failure to file a corrected information return in the same manner as the corresponding original will be deemed a failure to correct the corresponding original information return such that the filer will not receive the benefit of a reduced penalty under § 301.6721–1(b) for that corrected information return.

6. Proposed § 301.6011–3, Rules for Filing Partnership Returns Electronically

Section 301.6011–3 prescribes standards for determining whether a partnership must file its partnership return electronically. In 2018, the TTCA amended section 6011(e) to authorize the Secretary to incrementally reduce, by regulation, the electronic-filing threshold for partnerships. When section 2301 of the TFA amended that particular statute again in 2019, to further reduce the electronic-filing threshold for partnerships, the Secretary had not yet promulgated regulations to implement that reduced-threshold rule for partnerships. As discussed in this preamble, these proposed regulations do not include a special electronic-filing threshold for partnerships because the final regulations are not expected to be applicable before the 2022 filing season, at which point the special rule for partnerships will be phased out. See section 2.F., Special electronic-filing threshold for partnerships of any size. For returns required to be filed during calendar years after 2021, section 2301 of the TFA authorizes the Secretary to reduce the electronic-filing threshold to 10 for all persons, including partnerships. These proposed regulations would amend § 301.6011–3(a) to reduce the electronic-filing threshold to 10 returns for any partnership, in accordance with section 6011(e), as amended by the TFA. In addition, for all the reasons discussed in this preamble, the proposed regulations would add a new paragraph (a)(5) to § 301.6011–3 that provides that all returns of any type, including partnership returns, excise-tax returns, employment-tax returns, and information returns (but not including schedules required to be attached to or included with a partnership return), are counted in the aggregate for purposes of determining whether a partnership of any size meets the electronic-filing threshold of 10 returns in a calendar year, and thus must file its partnership return electronically. See sections 2.D., Aggregation of returns to determine whether the electronic-filing threshold is met; and 2.G., Special electronic-filing rule for partnerships having more than 100 partners. These rules relating to the requirements for determining when a partnership is required to file its partnership return electronically do not

limit the application of any other statute affecting partnership returns that must be filed electronically, such as section 6033(n), which requires a partnership return filed by a section 501(d) apostolic organization to be filed electronically.

7. Proposed § 301.6011–5, Rules for Filing Corporate Income Tax Returns Electronically

Section 301.6011–5 prescribes standards for determining whether a corporation must file its income tax returns electronically and requires large corporations to file the corporate income tax return electronically if the corporation is required to file during the calendar year at least 250 returns of any type. The regulation, however, applies only to those corporations that report total assets at the end of the corporate taxable year of $10 million or more on Schedule L of their Form 1120. Section 2301 of the TFA amended section 6011(e) to authorize the Secretary to prescribe regulations to reduce the number of returns that a person may be required to file during a calendar year before the Secretary may impose an electronic-filing requirement. These proposed regulations would remove references to the 250-return threshold and reduce the electronic-filing threshold for corporate income tax returns to 10, for returns required to be filed during calendar years after 2021, in accordance with section 6011(e), as amended by the TFA. In addition, the Treasury Department and the IRS propose to remove the $10 million rule, making the regulation applicable to all corporations regardless of reportable assets. The $10 million rule was never required by the Code; rather, the Treasury Department and the IRS prescribed the rule in 2007 to help ensure that electronic-filing burdens and costs were appropriate, given the existing limits and accessibility to electronic-filing technology at that time. With the current prevalence and accessibility of electronic filing even for small businesses, as well as the benefits of quicker return processing, the $10-million rule is no longer needed. Accordingly, the proposed regulations would require that any corporation required to file a corporate income tax return under § 1.6012–2, regardless of the corporation's reported total assets at the end of its taxable year, file that return electronically if the corporation is required to file at least 10 returns of any type during calendar years after 2021. The proposed regulations would also update the example to reflect these changes. The proposed regulations do not change the existing rule in § 301.6011–5 that all returns of any type are counted in determining whether a corporation is required to file its income tax return electronically.

8. Proposed § 301.6037–2, Required Use of Electronic Form for Returns of Electing-Small Business Corporation

Section 301.6037–2 prescribes standards for determining whether an S corporation must file its S corporation return electronically. Section 301.6037–2 requires S corporations to file their corporate income tax return electronically if the corporation is required to file during the calendar year at least 250 returns of any type, but the regulation applies only to those S corporations that report total assets at the end of the corporation's taxable year that equal or exceed $10 million on Schedule L of Form 1120–S.

Section 2301 of the TFA amended section 6011(e), authorizing the IRS to change the 250-return threshold to 10, for returns required to be filed during calendar years after 2021. These proposed regulations would remove references to the 250-return threshold and reduce the electronic-filing threshold for S corporations to 10 in accordance with section 6011(e), as amended by the TFA. In addition, the Treasury Department and the IRS propose to remove the $10 million rule for the same reasons that it is eliminating the rule for corporations. See section 7, Proposed § 301.6011–5, Rules for Filing Corporate Income Tax Returns Electronically. With the current prevalence and accessibility of e-filing, as well as the benefits of quicker processing of returns, the $10 million rule is no longer needed. Accordingly, the proposed regulations would require that any S corporation required to file an S-corporation return under § 1.6037–1, regardless of the corporation's reported total assets at the end of its taxable year, file its income tax return electronically if the corporation is required to file at least 10 returns of any type during the calendar year. The proposed regulations would also update the example illustrating this rule to reflect these changes.

9. Proposed §§ 1.6033–4 and 301.6033–4, Required Filing in Electronic Form for Returns by Organizations Required To File Returns Under Section 6033

Section 1.6033–4 provides that the return of an organization that is required to be filed electronically under § 301.6033–4 must be filed in accordance with IRS revenue procedures, publications, forms, or instructions, including those posted electronically.

Section 301.6033–4 provides that an organization required to file a return under section 6033 on Form 990 must file its Form 990 electronically if the organization is required to file during the calendar year at least 250 returns of any type and if the organization has total assets as of the end of the taxable year of $10 million or more. It also provides that any organization (regardless of total assets) required to file Form 990–PF must file its Form 990–PF electronically if it is required to file at least 250 returns of any type during the calendar year.

In accordance with section 3101 of the TFA, these proposed regulations would amend §§ 1.6033–4 and 301.6033–4 to replace the term ''magnetic media'' with ''in electronic form.'' These proposed regulations would also amend § 301.6033–4 to remove any references to thresholds that establish a requirement to file electronically because the TFA now requires that any organization required to file a return under section 6033 must file such return in electronic form. Likewise, the proposed regulations would amend § 301.6033–4 by removing the following paragraphs: Paragraph (d)(1), which defines the term ''magnetic media''; paragraph (d)(3), which defines the term ''determination of 250 returns''; and paragraph (e), which illustrates by example how the 250 number is determined. In addition, the proposed regulations would remove § 301.6033–4(b), which provides that the Commissioner may grant waivers of the electronic-filing requirement.

Section 3101 of the TFA does not provide for any waiver of or alternate method to the electronic-filing requirements for returns required to be filed under section 6033. Accordingly, these proposed regulations would amend § 301.6033–4 by removing paragraph (b) that provides for a waiver of the requirements.

Finally, these proposed regulations would amend § 301.6033–4(d)(2) to include Form 990–EZ, ''Short Form Return of Organization Exempt From Income Tax,'' as a return required to be filed under section 6033, clarifying that section 3101 of the TFA mandates that all returns required to be filed under section 6033 must be filed in electronic form.

10. Proposed § 53.6011–1(c) Deletion, Joint Filing of a Form 4720 Return

Section 3101(a) of the TFA amended section 6033(n) to provide that any exempt organization required to file a return under section 6033 must file such return in electronic form. Section 1.6033–2(a)(2) provides, under the

broad authority of section 6033(a)(1) (requiring every organization exempt from taxation under section 501(a) to file an annual return, stating specifically the items of gross income, receipts, and disbursements, and such other information for the purpose of carrying out the internal revenue laws as the Secretary may by forms or regulations prescribe), that every private foundation must file Form 990–PF, *Return of Private Foundation,* as its annual information return. In the case of a private foundation liable for tax under chapter 42, such information as is required by Form 4720 is to be furnished by the private foundation as part of its annual information return. See § 1.6033–2(a)(2)(ii)(J). The preamble to the final regulations adding § 1.6033–2(a)(2)(ii)(J) specifically noted that Form 4720, when filed by a private foundation, is part of the annual information return required to be filed under section 6033 as well as a tax return required to be filed under section 6011. Accordingly, Form 4720 filed by a private foundation as part of the Form 990–PF is a return required to be filed under section 6033 and is thus required to be filed in electronic form as a return required under section 6033(n). For the electronic-filing requirement for persons not described under section 509(a) as a private foundation, see section 16 of this preamble, Proposed § 301.6011–12, Required Use of Electronic Form for Returns of Certain Excise Taxes Under Chapters 41 And 42 of the Internal Revenue Code.

If Form 4720 is filed by a private foundation (or by a trust described in section 4947(a)(2)) with respect to a transaction to which other persons are required to file under § 53.6011–1(b) (persons liable for excise tax imposed by Chapters 41 and 42 of the Code), and if the other persons' tax years are the same as the foundation's or trust's, § 53.6011–1(c) allows the private foundation and such other persons to file a joint Form 4720, and, to the extent applicable, that form will be considered as the other persons' return for purposes of complying with the filing requirement under § 53.6011–1(b). This current regulatory permission to jointly file Form 4720, however, is incompatible with the requirement under section 6033(n) to file the return electronically. Accordingly, because the Form 4720 cannot be filed jointly in electronic form, the proposed regulations would delete § 53.6011–1(c). Disqualified persons thus will no longer be able to meet their tax filing obligation under § 53.6011–1(b) by the joint-filing process.

Notice 2021–01, 2021–2 I.R.B. 315 (January 11, 2021), announced the IRS's intent to remove § 53.6011–1(c) because the amendments the TFA made to sections 6104 (that any annual return required to be filed electronically under section 6033(n) must be made available by the Secretary to the public as soon as practicable in a machine-readable format) and 6033 rendered unfeasible the ability for a private foundation and other persons to jointly file the same Form 4720 electronically. Notice 2021–01 was first released to the public on December 16, 2020, and substantially described the expected contents of the proposed amendments to § 53.6011–1, in accordance with section 7805(b)(1)(C). Thus, the proposed changes to § 53.6011–1 described in this section are proposed to apply retroactively as of January 1, 2021, as allowed by section 7805(b)(1)(C).

11. Proposed § 301.6057–3, Required Use of Electronic Form for Filing Requirements Relating to Deferred Vested Retirement Benefit

Section 6057(a) requires the plan administrator (within the meaning of section 414(g)) of each plan, to which the vesting standards of section 203 of the Employee Retirement Income Security Act of 1974 (ERISA) apply for a plan year, to file, within the time prescribed by regulations, a registration statement with the Secretary. The registration statement must set forth the following information relating to the plan: (1) The name of the plan; (2) the name and address of the plan administrator; (3) the name and identifying information of plan participants who separated from service covered by the plan and are entitled to deferred vested retirement benefits; and (4) the nature, amount, and form of deferred vested retirement benefits to which the plan participants are entitled. The form used to satisfy the reporting requirements under section 6057 is Form 8955–SSA, *Annual Registration Statement Identifying Separated Participants with Deferred Vested Benefits.*

Section 6057(b) provides that any plan administrator required to register under section 6057(a) must, within the time prescribed by regulations, also notify the Secretary of any change in the name of the plan or the name and address of the plan administrator, the termination of the plan, or the merger or consolidation of the plan with any other plan or its division into two or more plans.

Section 301.6057–3 provides that a registration statement required to be filed under section 6057(a) or a notification required to be filed under section 6057(b) must be filed electronically if the filer is required by the Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. For the reasons discussed in this preamble, and consistent with section 6011(e), as amended by the TFA, these proposed regulations would remove references to the 250-return threshold and would reduce the electronic-filing threshold to 10 for registration statements required to be filed under section 6057(a) and notifications required under section 6057(b) with respect to an employee benefit plan for any plan year that begins after December 31, 2021 (but only for filings with a filing deadline, not taking into account extensions, after July 31, 2022). See section 2.C., Amending the electronic-filing threshold.

12. Proposed § 301.6058–2, Required Use of Electronic Form for Filing Requirements Relating to Information Required in Connection With Certain Plans of Deferred Compensation

Section 6058(a) generally requires that every employer maintaining a pension, annuity, stock bonus, profit-sharing, or other funded plan of deferred compensation, or the plan administrator (within the meaning of section 414(g)) of the plan, file an annual return stating such information as the Secretary may by regulations prescribe with respect to the qualification, financial condition, and operations of the plan. The reporting requirement under section 6058(a) is satisfied by filing a return in the Form 5500 series. The Form 5500, *Annual Return/Report of Employee Benefit Plan,* the Form 5500–SF, *Short Form Annual Return/Report of Small Employee Benefit Plan,* and Form 5500–EZ, *Annual Return of A One-Participant (Owners/Partners and Their Spouses) Retirement Plan or A Foreign Plan,* make up the Form 5500 series.

Section 301.6058–2(a) provides that a return required to be filed under section 6058 with respect to an employee benefit plan must be filed electronically if the filer is required by the Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. For the reasons discussed in this preamble, and in accordance with section 6011(e), as amended by the TFA, these proposed regulations would remove references to the 250-return threshold and reduce the electronic-filing threshold to 10 for returns required to be filed under section 6058 with respect to an employee benefit plan for any plan year that begins after December 31, 2021 (but

only for filings with a filing deadline, not taking into account extensions, after July 31, 2022). See section 2.C., Amending the electronic-filing threshold. In addition, these proposed regulations would provide a cross reference, under § 301.6058–2(d)(3), Calculating the number of returns, to new section 6011(e)(6) to alert taxpayers that information regarding each plan for which information is provided on a combined annual return to satisfy the requirements under section 6058 is treated as a separate return for purposes of determining the electronic-filing threshold.

Under section 104 of ERISA, the plan administrator of a plan described in section 6058(a) of the Code that is also an employee pension benefit plan within the meaning of section 3(2) of ERISA must file an annual report on Form 5500, *Annual Return/Report of Employee Benefit Plan,* or Form 5500–SF, *Short Form Annual Return/Report of Small Employee Benefit Plan* (and all attachments to those forms, including Schedules SB and MB) electronically using the Department of Labor's EFAST2 system, without regard to the number of returns the filer is required to file under the Code. The Department of Labor has advised the Treasury Department and the IRS that this proposed regulation does not affect the obligations of any person required to file an annual report electronically under 29 CFR 2520.104a–2 and section 104 of ERISA. An electronic filing on Form 5500 or Form 5500–SF also satisfies any obligation to file such forms using electronic form under section 6011 of the Code. An employer that maintains a one-participant or foreign plan (which is not subject to section 104 of ERISA) or the plan administrator of the plan may satisfy the annual return filing requirements under section 6058(a) of the Code by filing a Form 5500–EZ, *Annual Return of A One-Participant (Owners/Partners and Their Spouses) Retirement Plan or A Foreign Plan,* which is required to be filed electronically using the Department of Labor's EFAST2 system only if the employer or plan administrator is otherwise required to file using electronic form under section 6011.

13. Proposed § 301.6059–2, Required Use of Electronic Form for Filing Requirements Relating to Periodic Report of Actuary

Section 6059(a) generally requires that a plan administrator (as defined in section 414(g)) of each defined benefit plan to which section 412 applies file the actuarial report described in section 6059(b) for the first plan year for which section 412 applies to the plan and for each third plan year thereafter (or more frequently if the Secretary determines that more frequent reports are necessary). The reporting requirements under section 6059(a) and (b) are satisfied by filing Schedule SB (Form 5500), *Single Employer Defined Benefit Plan Actuarial Information* and Schedule MB (Form 5500), *Multiemployer Defined Benefit Plan and Certain Money Purchase Plan Actuarial Information.* Section 301.6059–2 provides that an actuarial report required to be filed under section 6059 with respect to an employee benefit plan must be filed electronically if the filer is required by the Code or regulations to file at least 250 returns during the calendar year that includes the first day of the plan year. For the reasons discussed in this preamble, and in accordance with section 6011(e), as amended by the TFA, these proposed regulations would remove references to the 250-return threshold and would reduce the electronic-filing threshold to 10, for actuarial reports required to be filed under section 6059 with respect to an employee benefit plan for any plan year that begins after December 31, 2021 (but only for filings with a filing deadline, not taking into account extensions, after July 31, 2022). See section 2.C., Amending the electronic-filing threshold. The Department of Labor has advised the Treasury Department and the IRS that the electronic-filing threshold under section 6011(e) does not affect the obligation of a plan administrator or plan sponsor to file electronically with the Department of Labor a Schedule SB or Schedule MB as an attachment to the Form 5500, as required by 29 CFR 2520.104a–2 and section 104 of ERISA.

14. Proposed § 301.6011–10, Certain Organizations, Including Trusts, Required To File Unrelated Business Income Tax Returns in Electronic Form

Section 3101(b)(2) of the TFA amended section 6011 to redesignate paragraph (h) as paragraph (i) and add new paragraph (h) that requires any organization required to file an annual return under section 6011 that relates to any tax imposed by section 511 to file such return in electronic form, effective for taxable years beginning after July 1, 2019. Section 3101 of the TFA does not provide for any waiver of or alternative method to the electronic-filing requirement for returns required to be filed under section 6011(h). The proposed regulations would add a new regulation under section 6011(h), § 301.6011–10, in accordance with the TFA, to require any organization described in section 511(a)(2) subject to the tax under section 511(a)(1) or any trust described in section 511(b)(2) subject to the tax under section 511(b)(1) on their respective unrelated business taxable income to file their unrelated business income tax returns electronically.

15. Proposed § 301.6011–11, Required Use of Electronic Form for Returns for Certain Tax-Advantaged Bonds

Under former sections 54AA and 6431(f) of the Code, issuers of qualified taxable bonds that provide a refundable federal tax credit payable directly to the issuer of the bond, such as build-America bonds, recovery zone economic development bonds, new clean renewable energy bonds, qualified energy conservation bonds, qualified zone academy bonds, and qualified school construction bonds, can elect to receive a direct payment from the federal government based upon a percentage of the interest payments on these bonds. Section 3.1 of Notice 2009–26, 2009–16 I.R.B. 833, 836 (April 20, 2009), and section 3 of Notice 2010–35, 2010–19 I.R.B. 660, 662 (May 10, 2010), provide that issuers of qualified bonds must submit a Form 8038–CP, *Return for Credit Payments to Issuers of Qualified Bonds,* to request payment of the amount of the credit within a prescribed time before or after each applicable interest payment date, depending on whether the bonds are fixed rate or variable rate. During 2013 to 2018, the IRS processed an average of $5 billion in direct payment requests; amounts paid on each return varied from less than $1,000 to more than $65 million. During 2019, state and local governments filed approximately 10,000 Forms 8038–CP in paper form. The IRS expects that it will continue to receive Forms 8038–CP from these issuers during the entire term of the bonds, which may be more than 20 years.

The proposed regulations would require filers who are required to file at least 10 returns of any type during the calendar year to file their Forms 8038–CP electronically, as directed by the form's instructions. This requirement would increase the timeliness and accuracy of processing these forms and promote IT modernization efforts. Proposed § 301.6011–11 would also provide that the Commissioner may grant individual waivers of the e-filing requirement of this section in cases of undue hardship. The Treasury Department and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver for filing Form 8038–CP electronically.

16. Proposed § 301.6011–12, Required Use of Electronic Form for Returns of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code

Section 2301 of the TFA amended section 6011(e), changing the 250-return threshold to a 10-return threshold for returns required to be filed in calendar years after 2021. The proposed regulations would add a new regulation under section 6011(e), § 301.6011–12, that would require the electronic filing of Form 4720, *Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code.* The proposed regulations would require a person to file the Form 4720 electronically if that person is required to file at least 10 returns of any type during the calendar year. Proposed § 301.6011–12 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship. The Treasury Department and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver for filing Form 4720 electronically. The proposed regulations relating to the requirements for determining whether a person must file its Form 4720 electronically would not limit the application of any other statute affecting Form 4720, such as section 6033(n), which requires a Form 4720 filed by organizations recognized as tax exempt under section 501(c)(3) and classified as private foundations under section 509(a) to be filed electronically, as discussed under section 10, Proposed § 53.6011–1(c) Deletion, Joint Filing of a Form 4720 Return.

17. Proposed § 301.6011–13, Required Use of Electronic Form for Split-Interest Trust Returns

Section 2301 of the TFA amended section 6011(e), changing the 250-return threshold to a 10-return threshold for returns required to be filed in calendar years after 2021. The proposed regulations would add a new regulation under section 6011(e), § 301.6011–13, that would require the filing of Form 5227, *Split-Interest Trust Information Return,* electronically. Forms 5227 are filed by split-interest trusts to report the trust's financial activities, including distributions to the beneficiaries. The proposed regulations would require a trust to file the Form 5227 electronically if the trust is required to file at least 10 returns of any type during the calendar year. Proposed § 301.6011–13 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship. The Treasury Department and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver for filing Form 5227 electronically.

18. Proposed § 301.6011–14, Required Use of Electronic Form or Other Machine-Readable Form for Material Advisor Disclosure Statements

The proposed regulations would add a new regulation under section 6011(e), § 301.6011–14, that would require the filing of Form 8918, *Material Advisor Disclosure Statement,* electronically or in other machine-readable form, in accordance with revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Section 6111 requires each material advisor with respect to any reportable transaction to make a return setting forth certain information with respect to the reportable transaction. Section 301.6111–3(d) clarifies that the return required to be filed under section 6111(a) is the Form 8918. Form 8918 is currently filed on paper and must be mailed to the Office of Tax Shelter Analysis in Ogden, Utah. The proposed regulations would require a material advisor to file the Form 8918 electronically or in other machine-readable form if the material advisor is required to file at least 10 returns of any type during the calendar year, in accordance with section 6011(e), as amended by section 2301 of the TFA. This requirement would increase the timeliness and accuracy of processing the data on Form 8918, reduce postage costs, and promote IT modernization efforts. Proposed § 301.6011–14 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship. The Treasury Department and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver from filing Form 8918 electronically.

19. Proposed § 301.6011–15, Required Use of Electronic Form for Withholding Tax Returns

The proposed regulations would add a new regulation under section 6011(e), § 301.6011–15, that would require the filing of Form 1042, *Annual Withholding Tax Return for U.S. Source Income of Foreign Persons,* electronically in accordance with revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Sections 1441 and 1442 require withholding agents to withhold tax from payments made to foreign persons with respect to certain U.S. source income and to report those payments and the tax withheld for each recipient. Section 1.1461–1(c) specifies that the reporting be on Form 1042–S, *Foreign Persons' U.S. Source Income Subject to Withholding.* In addition, § 1.1461–1(b) requires withholding agents to make an annual income tax return on Form 1042 that reports the aggregate income paid and taxes withheld for the preceding calendar year.

The IRS verifies the amount of withholding reported on Form 1042 and deposited with the IRS against amounts reported as withheld on Forms 1042–S. Form 1042–S is already required to be electronically filed to the extent provided under § 301.6011–2 for a withholding agent that is not a financial institution. But the Form 1042 is not required to be electronically filed. To increase the timeliness and accuracy of processing refunds and credits claimed by foreign persons that have amounts withheld and reported on Form 1042–S, proposed § 301.6011–15 would require Form 1042 filers—except for individuals, estates, or trusts—to file Form 1042 electronically if they are required to file 10 or more returns of any type during the calendar year, in accordance with section 6011(e), as amended by section 2301 of the TFA. Proposed § 301.6011–15 would also require partnerships with more than 100 partners to file their Forms 1042 electronically, regardless of the number of returns the partnership is required to file during the calendar year. Proposed § 301.6011–15 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship.

20. Proposed § 301.6012–2, Required Use of Electronic Form for Income Tax Returns of Certain Political Organizations

Section 2301 of the TFA amended section 6011(e), changing the 250-return threshold to a 10-return threshold for returns required to be filed in calendar years after 2021. The proposed regulations would add a new regulation under sections 6011(e) and 6012(a), § 301.6012–2, to require the filing of Form 1120–POL, *U.S. Income Tax Return for Certain Political Organizations* electronically. The Form 1120–POL is filed by political organizations, described in section 527 of the Code, to report income not specifically excluded from tax under section 527 and by exempt organizations subject to tax under section 527(f)(1) of the Code. The

proposed regulations would require an organization to file the Form 1120–POL electronically if the organization is required to file at least 10 returns of any type during the calendar year. Proposed § 301.6012–2 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship. The Treasury Department and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver for filing Form 1120–POL electronically.

21. Proposed § 54.6011–3, Required Use of Electronic Form for the Filing Requirements for the Return for Certain Excise Taxes Related to Employee Benefit Plans

The proposed regulations would add a new regulation under section 6011(e), § 54.6011–3, to require the filing of Forms 5330, *Return of Excise Taxes Related to Employee Benefit Plans,* electronically. Section 2301 of the TFA amended section 6011(e), changing the 250-return threshold to a 10-return threshold for returns required to be filed during calendar years after 2021. The proposed regulations would require a filer to file the Form 5330 electronically if the filer is required to file at least 10 returns of any type during the calendar year. Proposed § 54.6011–3 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship. The Treasury Department and the IRS anticipate issuing guidance that will set forth procedures whereby a taxpayer may request a hardship waiver for filing Form 5330 electronically.

22. Proposed § 1.1461–1, Payment and Returns of Tax Withheld

Section 1.1461–1 prescribes requirements for withholding agents to file information returns with respect to U.S. source income of foreign persons. Section 1.1461–1(c)(5) provides that a withholding agent that makes 250 or more Form 1042–S information returns for a taxable year must file those forms electronically as required under § 301.6011–2(b). The proposed regulations would amend § 1.1461–1 to remove paragraph (c)(5) because the electronic-filing requirement for Form 1042–S is contained in § 301.6011–2(b) and the 250-return threshold would no longer apply if the proposed amendments to § 301.6011–2 are finalized in a Treasury decision.

23. Proposed § 1.1474–1, Liability for Withheld Tax and Withholding Agent Reporting

Section 1.1474–1 provides rules for withholding agents making payments under chapter 4 of the Code. The first sentence in § 1.1474–1(e) provides that withholding agents that are not financial institutions and that are required to file 250 or more Forms 1042–S for a taxable year must file those forms electronically, referencing § 301.6011–2(b). The proposed regulations would amend § 1.1474–1 to remove the first sentence in § 1.1474–1(e) because the electronic-filing requirement for Form 1042–S is contained in § 301.6011–2(b) and the 250-return threshold would no longer apply if the proposed amendments to § 301.6011–2 are finalized in a Treasury decision.

24. Proposed § 301.1474–1, Required Use of Electronic Form for Financial Institutions Filing Form 1042, Form 1042–S, or Form 8966

These proposed regulations would amend § 301.1474–1 to add a requirement that a financial institution must file its Form 1042 electronically, without regard to the number of returns required to be filed during the calendar year, in accordance with section 6011(e)(4). The existing provision in § 301.1474–1(b), which provides that the Commissioner may grant individual waivers of the requirements of § 301.1474–1 in cases of undue hardship, would also apply to the proposed electronic-filing requirement relating to Form 1042.

25. Proposed § 1.6050M–1, Information Returns Relating to Persons Receiving Contracts From Certain Federal Executive Agencies

Section 1.6050M–1 requires federal executive agencies who enter into certain contracts, as defined under § 1.6050M–1(b)(2), to file information returns with respect to those contracts. Under § 1.6050M–1(d), the information returns must be filed on a quarterly basis; in addition, if the federal executive agency, on any October 1, expects to enter into 250 or more contracts during the one-year period beginning on October 1, it must file the information returns electronically.

Section 2301 of the TFA amended section 6011(e), authorizing the IRS to change the 250-return threshold to 10, for returns required to be filed during calendar years after 2021. For the reasons discussed in this preamble, and consistent with section 6011(e), as amended by the TFA, these proposed regulations would remove references to the 250-return threshold under § 1.6050M–1 and would reduce the electronic-filing threshold from 250 to 100, for information returns required to be filed during calendar year 2022, and from 100 to 10, for information returns required to be filed during calendar years after 2022.

Proposed § 1.6050M–1 would also provide that the Commissioner may grant individual waivers of the requirements of this section in cases of undue hardship.

26. Proposed § 1.6045–4, Information Returns Relating to Persons Receiving Contracts From Certain Federal Executive Agencies

Section 1.6045–4 requires a real estate reporting person to file information returns with respect to real-estate transactions. Section 1.6045–4(k) provides rules for filing these returns electronically. The form used to report these transactions is a form covered under § 301.6011–2(b)(1). Section 301.6011–2 provides the rules for electronically filing the forms listed in § 301.6011–2(b)(1). These proposed regulations would thus remove paragraph (k) from § 1.6045–4 because the electronic-filing requirement is contained in § 301.6011–2.

27. Withdrawal of May 2018 Proposed Regulations

In light of the TFA, the Treasury Department and the IRS withdraw the May 2018 proposed regulations under section 6011(e) because those proposed regulations interpret a provision of the Code that has been amended. The Treasury Department and the IRS have determined that the amendments made to section 6011(e) by the TFA require guidance to be issued by regulations. Withdrawing the proposed regulations and reissuing new proposed regulations ensure that all persons affected by the proposed regulations will have a meaningful opportunity to publicly comment.

Special Analyses

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations.

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. Although these rules may affect a substantial

number of small entities, for the reasons discussed in the following paragraphs, the economic impact is not significant.

Under section 6011(e) of the Code and §§ 1.6050M–1, 301.6011–2, 301.6011–3, 301.6011–5, 301.6037–2, 301.6057–3, 301.6058–2, and 301.6059–2, filers are already required to file returns and statements electronically if, during a calendar year, they are required to file 250 or more returns. The eight proposed rules—§§ 1.6050M–1, 301.6011–2, 301.6011–3, 301.6011–5, 301.6037–2, 301.6057–3, 301.6058–2, and 301.6059–2—would lower the 250-return threshold as authorized by section 6011(e), as amended by section 2301 of the TFA. A filer may request that the IRS waive the electronic-filing requirement if the filer's cost to comply with the rule would cause a financial hardship. The IRS routinely grants meritorious hardship waiver requests. Accordingly, the economic burden on the limited number of small entities that are not currently filing electronically will be slight; and small entities that would experience a hardship because of these seven proposed rules may seek a waiver.

Under section 6050I of the Code and §§ 1.6050I–1 and 1.6050I–2, filers are required to file Forms 8300 if, in the course of their trade or business, they receive more than $10,000 in cash in one transaction or in two or more related transactions. The proposed rule under § 301.6011–2(b)(3) would require filers of Forms 8300 to file those forms electronically if such filers are also required to file returns electronically under paragraphs (b)(1) and (b)(2) of § 301.6011–2. The Treasury Department and the IRS expect filers of Form 8300 to use FinCEN's BSA E-Filing System, which is free, requiring only an internet connection. The economic impact on small entities should thus not be significant. Nonetheless, small entities that would experience a hardship because of this proposed rule may seek a hardship waiver.

Under section 6011(e)(4) of the Code and § 301.1474–1, financial institutions defined in section 1471(d)(5) of the Code already are required to electronically file Forms 1042–S. The proposed rule under § 301.1474–1(a) would extend this filing requirement to Forms 1042 filed by the same financial institutions. The economic impact on small entities should thus not be significant. Nonetheless, small entities that would experience a hardship because of this proposed rule may seek a hardship waiver.

Under section 6011(h) of the Code, as amended by section 3101 of the TFA, organizations required to file annual returns relating to any tax imposed by section 511 must file those returns in electronic form. The proposed regulation § 301.6011–10 implements this statutory requirement. The economic impact of the proposed regulation should thus be insignificant.

Under section 6033(n), as amended by section 3101 of the TFA, organizations required to file returns under section 6033 must file those returns in electronic form. The proposed regulations under §§ 1.6033–4, 53.6011–1, and 301.6033–4 implement this statutory requirement. The economic impact of these proposed regulations should thus be insignificant.

The seven proposed regulations under §§ 54.6011–3, 301.6011–11, 301.6011–12, 301.6011–13, 301.6011–14, 301.6011–15, and 301.6012–2 would require electronic filing for certain returns not currently required to be filed electronically. Because electronic filing has become more common, accessible, and economical, the economic impact of these proposed rules on small entities should be insignificant. But if the cost to comply with these electronic-filing requirements would cause a financial hardship, an entity may request a waiver. The IRS routinely grants meritorious hardship waiver requests. Accordingly, the burden on small entities affected by these rules will be slight.

Accordingly, it is hereby certified that these proposed regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This regulation does not include any federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

Executive Order 13132 (titled Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law, within the meaning of the Executive Order.

Pursuant to section 7805(f) of the Code, this proposed regulation has been submitted to the Chief Counsel for the Office of Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** section. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. Any comments submitted will be available at *www.regulations.gov* or upon request.

The public hearing is being held by teleconference on September 22, 2021 at 10 a.m. EST. Requests to speak and outlines of topics to be discussed at the public hearing must be received by September 21, 2021. If no outlines are received by September 21, 2021, the public hearing will be cancelled. Requests to attend the public hearing must be received by 5:00 p.m. EST on September 20, 2021. The telephonic hearing will be made accessible to people with disabilities. Requests for special assistance during the telephonic hearing must be received by September 20, 2021.

Drafting Information

The principal author of these proposed regulations is Casey R. Conrad of the Office of the Associate Chief Counsel (Procedure and Administration). Other personnel from the Treasury Department and the IRS participated in the development of the regulations.

Statement of Availability of IRS Documents

IRS revenue procedures, notices, and other guidance cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

Withdrawal of Proposed Regulations

Under the authority of 26 U.S.C. 7805, § 301.6011–2 and § 301.6721–1 of the notice of proposed rulemaking (REG–102951–16) that was published in the

Federal Register on Thursday, May 31, 2018 (83 FR 24948) is withdrawn.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 53

Excise taxes, Foundations, Investments, Lobbying, Reporting and recordkeeping requirements.

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1, 53, 54 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding the following entries in numerical order:

Authority: 26 U.S.C. 7805 * * *

Section 1.6033–4 also issued under 26 U.S.C. 6033.

Section 1.6037–2 also issued under 26 U.S.C. 6037.

* * * * *

■ **Par. 2.** Section 1.1461–1 is amended by removing paragraph (c)(5) and revising paragraph (i) to read as follows:

§ 1.1461–1. Payment and returns of tax withheld.

* * * * *

(i) *Applicability date.* Except as provided in paragraph (c)(2)(iii) of this section, this section applies to returns required for payments made on or after [the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**]. (For payments made before [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**] and on or after January 1, 2022, see this section as in effect and contained in 26 CFR part 1, as revised April 1, 2021. For payments made before January 1, 2022, see this section as in effect and contained in 26 CFR part 1, as revised April 1, 2020.)

■ **Par. 3.** Section 1.1471–0 is amended by revising the entries in the table of contents for § 1.1474–1(e) and (j) and § 301.1474–1(d)(1) and (e) to read as follows:

§ 1.1471–0 Outline of regulation provisions for sections 1471 through 1474.

* * * * *

§ 1.1474–1 Liability for withheld tax and withholding agent reporting.

* * * * *

(e) Reporting in electronic form.

* * * * *

(j) Applicability date.

* * * * *

§ 301.1474–1 Required use of electronic form for financial institutions filing Form 1042, Form 1042–S, or Form 8966.

* * * * *

(d) * * *

(1) Magnetic media or electronic form.

* * * * *

(e) Applicability date.

■ **Par. 4.** Section 1.1474–1 is amended by revising paragraphs (e) and (j) to read as follows:

§ 1.1474–1 Liability for withheld tax and withholding agent reporting.

* * * * *

(e) *Reporting in electronic form.* See § 301.6011–2(b) of this chapter for the requirements of a withholding agent that is not a financial institution with respect to the filing of Forms 1042–S in electronic form. See § 301.1474–1(a) of this chapter for the requirements applicable to a withholding agent that is a financial institution with respect to the filing of Forms 1042–S in electronic form.

* * * * *

(j) *Applicability date.* This section applies to returns required for payments made on or after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**]. (For the rules that apply before [the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**] and on or after January 6, 2017, see this section as in effect and contained in 26 CFR part 1, as revised April 1, 2021.)

■ **Par. 5.** Section 1.6033–4 is revised to read as follows:

§ 1.6033–4 Required filing in electronic form for returns by organizations required to file returns under section 6033.

(a) *In general.* The return of an organization that is required to be filed in electronic form under § 301.6033–4 of this chapter must be filed in accordance with revenue procedures, publications, forms, instructions, or other guidance.

(b) *Applicability date.* The rules of this section apply for returns required to be filed for taxable years ending on or after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 6.** Section 1.6037–2 is revised to read as follows:

§ 1.6037–2 Required use of electronic form for income tax returns of electing small business corporations.

(a) *In general.* The return of an electing small business corporation that is required to be filed electronically under § 301.6037–2 of this chapter must be filed in accordance with Internal Revenue Service revenue procedures, publications, forms, or instructions, including those posted electronically.

(b) *Applicability date.* The rules of this section apply for returns required to be filed for taxable years ending on or after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 7.** Section 1.6045–2 is amended by revising paragraphs (g)(2) and (i) to read as follows:

§ 1.6045–2 Furnishing statement required with respect to certain substitute payments.

* * * * *

(g) * * *

(2) *Reporting in electronic form.* For information returns filed after December 31, 1996, see § 301.6011–2 of this chapter for rules relating to filing information returns in electronic form and for rules relating to waivers granted for undue hardship. A broker or barter exchange that fails to file a Form 1099 electronically, when required, may be subject to a penalty under section 6721 for each such failure. See paragraph (g)(4) of this section.

* * * * *

(i) *Applicability date.* This section applies to substitute payments received by a broker after December 31, 1984. The amendments to paragraph (c) of this section apply to payee statements due after December 31, 2014. For payee statements due before January 1, 2015, § 1.6045–2(c) (as contained in 26 CFR part 1, revised April 2013) shall apply. The amendments to paragraph (g)(2) of this section apply to information returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 8.** Section 1.6045–4 is amended by removing and reserving paragraph (k) and revising paragraph (s) to read as follows:

§ 1.6045–4 Information reporting on real estate transactions with dates of closing on or after January 1, 1991.

* * * * *

(s) *Applicability date.* This section applies for real estate transactions with dates of closing (as determined under paragraph (h)(2)(ii) of this section) that

occur on or after January 1, 1991. The amendments to paragraphs (b)(2)(i)(E), (b)(2)(ii) and (c)(2)(i) of this section apply to sales or exchanges of standing timber for lump-sum payments completed after May 28, 2009. The amendments to paragraph (m)(1) of this section apply to payee statements due after December 31, 2014. For payee statements due before January 1, 2015, § 1.6045–4(m)(1) (as contained in 26 CFR part 1, revised April 2013) shall apply. The removal of paragraph (k) of this section applies for information returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 9.** Section 1.6050I–0 is amended by revising the entry in the table of contents for § 1.6050I–1(d)(2)(ii) as follows:

§ 1.6050I–0 Table of contents.

* * * * *

(d) * * *

(2) * * *

(ii) Casinos exempt under 31 CFR 1010.970(c).

* * * * *

■ **Par. 10.** Section 1.6050I–1 is amended by:

■ 1. Revising paragraphs (a)(3)(ii), (c)(1)(iv), (d)(2)(i), (d)(2)(ii):

■ 2. In paragraph (d)(2)(iv), designating the example as paragraph (d)(2)(iv)(A);

■ 3. Revising newly designated paragraph (d)(2)(iv)(A) and adding paragraph (d)(2)(iv)(B);

■ 4. Revising paragraphs (e)(1) and (e)(3)(i); and

■ 5. Adding paragraph (h).

The revisions and additions read as follows:

§ 1.6050I–1 Returns relating to cash in excess of $10,000 received in a trade or business.

(a) * * *

(3) * * *

(ii) *Exception.* An agent who receives cash from a principal and uses all of the cash within 15 days in a cash transaction (second cash transaction) which is reportable under section 6050I or 5312 of title 31 of the United States Code and the regulations thereunder (31 CFR Chapter X), and who discloses the name, address, and taxpayer identification number of the principal to the recipient in the second cash transaction need not report the initial receipt of cash under this section.

* * * * *

(c) * * *

(1) * * *

(iv) *Exception for certain loans.* A cashier's check, bank draft, traveler's check, or money order received in a designated reporting transaction is not treated as cash pursuant to paragraph (c)(1)(ii)(B)(*1*) of this section if the instrument constitutes the proceeds of a loan from a bank (as that term is defined in 31 CFR Chapter X).

* * * * *

(d) * * *

(2) * * * (i) *In general.* If a casino receives cash in excess of $10,000 and is required to report the receipt of such cash directly to the Treasury Department under 31 CFR 1021.310 or 1010.360 and is subject to the recordkeeping requirements of 31 CFR 1021.400, then the casino is not required to make a return with respect to the receipt of such cash under section 6050I and these regulations.

(ii) *Casinos exempt under 31 CFR 1010.970(c).* Under the authority of section 6050I(c)(1)(A), the Secretary may exempt from the reporting requirements of section 6050I casinos with gross annual gaming revenue in excess of $1,000,000 that are exempt under 31 CFR 1010.970(c) from reporting certain cash transactions to the Treasury Department under 31 CFR 1021.310 or 1010.360. The determination whether a casino which is granted an exemption under 31 CFR 1010.970(c) will be required to report under section 6050I will be made on a case by case basis, concurrently with the granting of such an exemption.

* * * * *

(iv) * * *

(A) *Example.* A and B are casinos having gross annual gaming revenue in excess of $1,000,000. C is a casino with gross annual gaming revenue of less than $1,000,000. Casino A receives $15,000 in cash from a customer with respect to a gaming transaction which the casino reports to the Treasury Department under 31 CFR 1021.310 and 1010.360. Casino B's hotel division receives $15,000 in cash from a customer in payment for accommodations provided to that customer at Casino B's hotel. Casino C receives $15,000 in cash from a customer with respect to a gaming transaction. Casino A is not required to report the transaction under section 6050I or these regulations because the exception for certain casinos provided in paragraph (d)(2)(i) of this section (casino exception) applies. Casino B's hotel division is required to report under section 6050I and these regulations because the casino exception does not apply to the receipt of cash by a nongaming business division. Casino C is required to report under section 6050I and these regulations because the casino exception does not apply to casinos having gross annual gaming revenue of $1,000,000 or less which do not have to report to the Treasury Department under 31 CFR 1021.310 and 1010.360.

(B) [Reserved]

* * * * *

(e) * * * (1) *Time of reporting.* The reports required by this section must be filed in accordance with the Form 8300 instructions and related publications by the 15th day after the date the cash is received. However, in the case of multiple payments relating to a single transaction (or two or more related transactions), see paragraph (b) of this section.

* * * * *

(3) * * * (i) *Where to file.* A person making a return of information under this section must file Form 8300 in accordance with the form instructions and related publications.

* * * * *

(h) *Applicability date.* The rules of this section apply for returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 11.** Section 1.6050I–2 is amended by revising paragraphs (c)(1)(i), (c)(3)(i), and (f) to read as follows:

§ 1.6050I–2 Returns relating to cash in excess of $10,000 received as bail by court clerks.

* * * * *

(c) * * *

(1) * * * (i) *In general.* The information return required by this section must be filed in accordance with the Form 8300 instructions and related publications by the 15th day after the date the cash bail is received.

* * * * *

(3) * * * (i) *Where to file.* Returns required by this section must be filed in accordance with the Form 8300 instructions and related publications. A copy of the information return required to be filed under this section must be retained for five years from the date of filing.

* * * * *

(f) *Applicability date.* The rules of this section apply for returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 12.** Section 1.6050M–1 is amended by revising paragraphs (d)(2), (d)(3), and (f) as follows:

§ 1.6050M–1 Information returns relating to persons receiving contracts from certain federal executive agencies.

* * * * *

(d) * * *

(2) *Form of reporting*—(i) *General rule concerning electronic filing.* The information returns required by this section with respect to contracts of a federal executive agency for each calendar quarter must be made in one submission (or in multiple submissions if permitted by paragraph (d)(4) of this section). Except as provided in paragraph (d)(2)(ii) of this section, the required returns must be made in electronic form (within the meaning of § 301.6011–2(a)(1)) in accordance with any applicable revenue procedure or other guidance promulgated by the Internal Revenue Service for the filing of such returns under section 6050M.

(ii) *Exceptions from electronic filing.* Any federal executive agency that, on October 1, has a reasonable expectation of entering into, during the one-year period beginning on that date, fewer than 100 contracts subject to the reporting requirements under this section that are to be filed during the calendar year 2022, or fewer than 10 contracts subject to the reporting requirements under this section that are to be filed during the calendar years after 2022, may make the information returns required by this section for each quarter of that one-year period on the prescribed paper Form 8596 in accordance with the instructions accompanying such form.

(iii) *Undue hardship.* The Commissioner may grant waivers of the electronic-filing requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under paragraph (a) of this section) and the period to which it applies.

(3) *Place of filing*—(i) *Returns in electronic form.* Information returns made under this section in electronic form must be filed with the Internal Revenue Service in accordance with any applicable revenue procedure or other guidance promulgated by the Internal Revenue Service relating to the filing of returns under section 6050M.

(ii) *Form 8596.* Information returns made on paper Form 8596 must be filed with the Internal Revenue Service at the location specified in the instructions for that form.

* * * * *

(f) *Applicability date*—(1) *Contracts required to be reported.* Except as otherwise provided in this paragraph (f), this section applies to each federal executive agency with respect to its contracts entered into on or after January 1, 1989 (including any increase in amount obligated on or after January 1, 1989, that is treated as a new contract under paragraph (e) of this section).

(2) *Contracts not required to be reported.* A federal executive agency is not required to report—

(i) Any basic or initial contract entered into before January 1, 1989,

(ii) Any increase contract action occurring before January 1, 1989, that is treated as a new contract under paragraph (e) of this section, or

(iii) Any increase contract action that is treated as a new contract under paragraph (e) of this section if the basic or initial contract to which that contract action relates was entered into before January 1, 1989, and—

(A) The increase occurs before April 1, 1990, or

(B) The amount of the increase does not exceed $50,000.

(3) *Illustration.* (i) If federal executive agency enters into an initial contract on December 1, 1988, and the amount of money obligated under the contract is increased by $55,000 on April 15, 1990, then (A) there is no reporting requirement with respect to the contract when entered into on December 1, 1988, and (B) the April 15, 1990, increase, which is treated as a new contract under paragraph (e) of this section, is subject to the reporting requirements of this section because it is considered to be a new contract entered into on April 15, 1990.

(ii) If the $55,000 increase had occurred before April 1, 1990, there would have been no reporting requirement with respect to that increase.

(4) *Filing requirements for contracts required to be reported.* The amendments to paragraphs (d)(2) and (d)(3) of this section apply for information returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

PART 53—FOUNDATION AND SIMILAR EXCISE TAXES

■ **Par. 13.** The authority citation for part 53 is amended by adding the following entry:

Authority: 26 U.S.C. 7805 * * *

Section 53.6011–1 also issued under 26 U.S.C. 6011.

* * * * *

■ **Par. 14.** Section 53.6011–1 is amended by:

■ 1. Removing paragraph (c).

■ 2. Redesignating paragraphs (d) and (e) as paragraphs (c) and (d), respectively.

■ 3. Adding a new paragraph (e).

The addition reads as follows:

§ 53.6011–1 General requirement of return, statement or list.

* * * * *

(e) *Applicability Date.* The rules of this section apply for any returns required to be filed under this section on or after January 11, 2021.

PART 54—PENSION EXCISE TAXES

■ **Par. 15.** The authority citation for part 54 is amended by adding the following entry:

Authority: 26 U.S.C. 7805 * * *

Section 54.6011–3 also issued under 26 U.S.C. 6011.

* * * * *

■ **Par. 16.** Section 54.6011–3 is added to read as follows:

§ 54.6011–3 Required use of electronic form for the filing requirements for the return for certain excise taxes related to employee benefit plans.

(a) *Excise tax returns required in electronic form.* Any employer or individual required to file an excise tax return on Form 5330, *Return of Excise Taxes Related to Employee Benefit Plans,* under § 54.6011–1 of this chapter must file the excise tax return electronically if the filer is required by the Internal Revenue Code or regulations to file at least 10 returns of any type during the calendar year that the Form 5330 is due. The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic filing requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds

the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 54.6011–1) and the period to which it applies.

(c) *Failure to file.* If a filer required to file the Form 5330 fails to file the report electronically when required to do so by this section, the filer is deemed to have failed to file the report. See generally section 6651(a)(1) for the penalty for the failure to file a tax return or to pay tax. For general rules relating to the failure to file tax return or to pay tax, see the regulations under 26 CFR 301.6651 (Regulations on Procedure and Administration).

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

(2) *Calculating the number of returns a filer is required to file*—(i) *In general.* For purposes of this section, a filer is required to file at least 10 returns during a calendar year if the filer is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(ii) *Definition of filer.* For purposes of this section, the term *filer* means the person required to report the tax on the Form 5330. For general rules on who is required to report the tax on the Form 5330, see the Instructions to the Form 5330.

(e) *Example.* The following example illustrates the provisions of paragraph (d)(2) of this section:

(1) In 2022, Employer A (the plan sponsor and plan administrator of Plan B) is required to file Form 5330 for its nondeductible contribution under section 4972 to Plan B. During the 2023 calendar year, Employer A is required to file 20 returns (including 19 Forms 1099–R *Distributions From Pensions, Annuities, Retirement, Profit-Sharing Plans, IRAs, Insurance Contracts, etc.* and one Form 5500 series *Annual Return/Report of the Employee Benefit Plan*). Plan B's plan year is the calendar year. Because Employer A is required to file at least 10 returns during the 2023 calendar year, Employer A must file the 2022 Form 5330 for Plan B electronically.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for any Form 5330 required to be filed for taxable years ending on or after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 17.** The authority citation for part 301 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 301.6011–10 also issued under 26 U.S.C. 6011.

Section 301.6011–11 also issued under 26 U.S.C. 6011.

Section 301.6011–12 also issued under 26 U.S.C. 6011.

Section 301.6011–13 also issued under 26 U.S.C. 6011.

Section 301.6011–14 also issued under 26 U.S.C. 6011.

Section 301.6011–15 also issued under 26 U.S.C. 6011.

Section 301.6012–2 also issued under 26 U.S.C. 6012.

* * * * *

Section 301.6057–3 also issued under 26 U.S.C. 6011 and 6057.

Section 301.6058–2 also issued under 26 U.S.C. 6011 and 6058.

Section 301.6059–2 also issued under 26 U.S.C. 6011 and 6059.

* * * * *

Section 301.6721–1 also issued under 26 U.S.C. 6011 and 6721.

* * * * *

■ **Par. 18.** Section 301.1474–1 is amended by:

■ 1. Revising the section heading.

■ 2. Revising paragraphs (a) through (c).

■ 3. Revising paragraph (d)(1).

■ 4. Adding a sentence at the end of paragraph (e).

The revisions and addition read as follows:

§ 301.1474–1 Required use of electronic form for financial institutions filing Form 1042, Form 1042–S, or Form 8966.

(a) *Financial institutions filing certain returns.* If a financial institution is required to file a Form 1042, *Annual Withholding Tax Return for U.S. Source Income of Foreign Persons,* (or successor form) under § 1.1474–1(c) of this chapter, the financial institution must file the return information required by the applicable forms and schedules electronically. If a financial institution is required to file a Form 1042–S, *Foreign Person's U.S. Source Income Subject to Withholding,* (or such other form as the IRS may prescribe) under § 1.1474–1(d) of this chapter, the financial institution must file the information required by the applicable forms and schedules electronically. Additionally, if a financial institution is required to file Form 8966, ''FATCA Report,'' (or such other form as the IRS may prescribe) to report certain information about U.S. accounts, substantial U.S. owners of foreign entities, or owner-documented FFIs as required under this chapter, the financial institution must file the required information in electronic form. Returns filed electronically must be made in accordance with applicable regulations, revenue procedures, publications, forms, instructions, and the *IRS.gov* internet site. In prescribing regulations, revenue procedures, publications, forms, and instructions, including those on the *IRS.gov* internet site, the Commissioner may direct the type of electronic filing.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 1.1474–1(c) or (d) of this chapter, or a Form 8966) and the period to which it applies.

(c) *Failure to file.* If a financial institution fails to file a Form 1042 electronically when required to do so by this section, the financial institution is deemed to have failed to file the return. (See section 6651 for the addition to tax for failure to file a return). In determining whether there is reasonable cause for failure to file the return, § 301.6651–1(c) and rules similar to the rules in § 301.6724–1(c)(3) (undue economic hardship related to filing information returns electronically) will apply. If a financial institution fails to file a Form 1042–S or a Form 8966 electronically when required to do so by this section, the financial institution is deemed to have failed to comply with the information reporting requirements under section 6721 of the Code. See section 6724(c) for failure to meet magnetic media requirements. In determining whether there is reasonable cause for failure to file the return,

§ 301.6651–1(c) and rules similar to the rules in § 301.6724–1(c)(3) (undue economic hardship related to filing information returns on magnetic media) will apply.

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(e) * * * This section applies to any Form 1042 (or successor form) filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 19.** Section 301.6011–2 is amended by:

■ 1. Revising paragraphs (a)(1).

■ 2. Revising paragraph (b).

■ 3. Revising the heading of paragraph (c) and paragraph (c)(1).

■ 4. Redesignating paragraph (c)(2) as (c)(6) and adding new paragraphs (c)(2) through (5).

■ 5. Revising newly redesignated paragraphs (c)(6)(i) and (ii).

■ 6. Revising paragraph (g).

The revisions and additions read as follows:

§ 301.6011–2 Required use of electronic form.

(a) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures or publications, or, in the case of returns filed with the Social Security Administration, Social Security Administration publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, or publications.

* * * * *

(b) *Returns required electronically.* (1) If the use of Form 1042–S, Form 1094 series, Form 1095–B, Form 1095–C, Form 1097–BTC, Form 1098, Form 1098–C, Form 1098–E, Form 1098–Q, Form 1098–T, Form 1099 series, Form 3921, Form 3922, Form 5498 series, Form 8027, Form W–2G, or other forms prescribed under paragraph (b)(4) of this section treated as forms specified in this paragraph (b)(1) is required by the applicable regulations or revenue procedures for the purpose of making an information return, the information required by the form must be submitted electronically, except as otherwise provided in paragraph (c) of this section. Returns filed electronically must be made in accordance with applicable revenue procedures, publications, forms, or instructions.

(2) If the use of Form W–2 (Wage and Tax Statement), Form 499R–2/W–2PR (Withholding Statement (Puerto Rico)), Form W–2VI (U.S. Virgin Islands Wage and Tax Statement), Form W–2GU (Guam Wage and Tax Statement), Form W–2AS (American Samoa Wage and Tax Statement), or other forms prescribed under paragraph (b)(4) of this section as treated as forms specified in this paragraph (b)(2) is required for the purpose of making an information return, the information required by the form must be submitted electronically, except as otherwise provided in paragraph (c) of this section. Returns described in this paragraph (b)(2) must be made in accordance with applicable Social Security Administration procedures or publications (which may be obtained from the local office of the Social Security Administration).

(3) If a person is required to make a return for the purpose of section 6050I, and such person is required to file returns described in paragraphs (b)(1) and (2) of this section electronically, then such person must also file the information required by section 6050I on Form 8300 electronically. Returns described in this paragraph (b)(3) must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website.

(4) The Commissioner may prescribe by revenue procedure that additional forms are treated, for purposes of this section, as forms specified in paragraphs (b)(1) or (2) of this section. In addition, the Commissioner may exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website.

(c) *Applicable number-threshold*—(1) *In general.* No person is required to file information returns electronically in a calendar year unless the person is required to file at least the applicable number of returns during that calendar year. Persons required to file fewer than the applicable number of returns during the calendar year may make the returns on the prescribed paper form or, alternatively, electronically in accordance with paragraph (b) of this section.

(2) *Machine-readable forms.* Returns made on a paper form under paragraph (c)(1) of this section must be machine-readable, as described in paragraph (a)(2) of this section, if applicable revenue procedures provide for a machine-readable paper form.

(3) *Calculating the applicable number*—(i) *In general.* For purposes of paragraph (c)(1) of this section, the applicable number is 100, for returns required to be filed during calendar year 2022, and 10, for returns required to be filed during calendar years after 2022.

(ii) *Special rule for partnerships.* Notwithstanding paragraph (c)(3)(i) of this section, a partnership with more than 100 partners is required to file its information returns covered under paragraph (b) of this section electronically.

(4) *Calculating the number of returns*—(i) *Aggregation of returns.* In calculating whether a person is required to file at least the applicable number of returns under paragraph (c)(3) of this section, all the information returns described in paragraphs (b)(1) and (b)(2) of this section required to be filed during the calendar year, are counted in the aggregate. Corrected information returns and information returns described in paragraph (b)(3) of this section are not taken into account in calculating whether a person is required to file at least the applicable number of returns.

(ii) *Corrected returns.* (A) If an original information return covered by paragraph (b) of this section is required to be filed electronically, any corrected information return corresponding to that original return must also be filed electronically.

(B) If an original information return is permitted to be filed on paper and is filed on paper, any corrected information return corresponding to that original return must be filed on paper.

(5) *Examples.* The provisions of paragraphs (c)(3) and (4) of this section are illustrated by the following examples:

(i) *Example 1.* During the 2023 calendar year, Company W, is required to file 5 Forms 1099–INT, *Interest Income,* and 5 Forms 1099–DIV, *Dividends and Distributions,* for a total of 10 returns covered by paragraph (b) of this section. The applicable number for returns required to be filed during calendar year 2023 is 10. Because Company W is required to file the applicable number of returns covered by paragraph (c)(3) of this section during the 2023 calendar year, Company W must file all its 2022 Forms 1099–INT and Forms 1099–DIV electronically.

(ii) *Example 2.* Same facts as paragraph (c)(5)(i) of this section (*Example 1*), except after electronically filing its 10 Forms 1099–

DIV and 1099–INT, Company W files 2 corrected Forms 1099–DIV and 4 corrected Forms 1099–INT. Because Company W electronically filed its original 2022 Forms 1099–DIV and 1099–INT, Company W must electronically file its corrected 2022 Forms 1099–DIV and 1099–INT.

(iii) *Example 3.* Same facts as paragraph (c)(5)(i) of this section (*Example 1*), except on May 16, 2023, Company W received cash in excess of $10,000 and must file a Form 8300 by May 31, 2023. Because Company W is required to file information returns covered under paragraphs (b)(1) and (2) of this section electronically during the 2023 calendar year, Company W must also file all its Forms 8300 electronically during the 2023 calendar year.

(iv) *Example 4.* Same facts as paragraph (c)(5)(i) of this section (*Example 1*), except Company W is not required to file any Forms 1099–INT during calendar year 2023. On December 19, 2022, Company W receives cash in excess of $10,000 and must file a Form 8300 by January 3, 2023. Because Company W is not required to file information returns covered under paragraphs (b)(1) and (b)(2) of this section electronically during the 2023 calendar year, Company W is not required to file this Form 8300 electronically.

(v) *Example 5.* During the 2023 calendar year, Partnership P, a partnership with 15 partners, is required to file 8 Forms 1099–MISC, *Miscellaneous Income,* and 5 Forms 1099–INT. The applicable number of returns required to be filed by partnerships during calendar year 2023 is 10. Because Partnership P is required to file at least the applicable number of returns covered by paragraph (b) of this section during the 2023 calendar year, Partnership P must electronically file all its 2022 Forms 1099–MISC and 1099–INT.

(6) * * *

(i) The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. Notwithstanding the foregoing, if an employer is required to make a final return on Form 941, or a variation thereof, and expedited filing of Forms W–2, Forms 499R–2/W–2PR, Forms W–2VI, Forms W–2GU, or Form W–2AS is required, the unavailability of the specifications for electronic filing will be treated as creating a hardship (see § 31.6071(a)–1(a)(3)(ii) of this chapter). A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under paragraph (b) of this section) and the period to which it applies.

(ii) The Commissioner may supplement the provisions of paragraph (c)(6)(i) of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website.

* * * * *

(g) *Applicability date.* The rules of this section apply for information returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 20.** Section 301.6011–3 is amended by:

■ 1. Revising the section heading.

■ 2. Revising paragraphs (a), (b), and (d)(1).

■ 3. Redesignating paragraph (d)(5) as (d)(6) and adding new paragraph (d)(5).

■ 4. Revising newly redesignated paragraph (d)(6).

■ 5. Revising paragraphs (e) and (f).

The revisions and addition read as follows:

§ 301.6011–3 Required use of electronic form for partnership returns.

(a) *Partnership returns required electronically.* (1) Except as otherwise provided in paragraph (b) of this section, a partnership required to file a partnership return pursuant to § 1.6031(a)–1 of this chapter, must file the information required by the applicable forms and schedules electronically, if:

(i) The partnership is required by the Internal Revenue Code or regulations to file at least 10 returns (as described in paragraph (d)(5) of this section) during the calendar year, or

(ii) the partnership has more than 100 partners during the partnership's taxable year.

(2) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 1.6031(a)–1 of this chapter) and the period to which it applies.

* * * * *

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(5) *Calculating the number of returns.* For purposes of this section, a partnership is required to file at least 10 returns if, during the calendar year ending with or within the taxable year of the partnership, the partnership is required to file at least 10 returns of any type, including income tax returns, employment tax returns, excise tax returns, and information returns (for example, Forms W–2 and Forms 1099, but not including schedules required to be included with a partnership return). In the case of a short-period return, a partnership is required to file at least the applicable number of returns if, during the calendar year in which the partnership's short taxable year ends, the partnership is required to file at least the applicable number of returns of any type, including information returns (for example, Forms W–2 and Forms 1099, but not including schedules required to be included with a partnership return), income tax returns, employment tax returns, and excise tax returns.

(6) *Partnerships with more than 100 partners.* A partnership has more than 100 partners if, over the course of the partnership's taxable year, the partnership had more than 100 partners, regardless of whether a partner was a partner for the entire year or whether the partnership had over 100 partners on any particular day in the year. For purposes of this paragraph (d)(6), however, only those persons having a direct interest in the partnership must be considered partners for purposes of determining the number of partners during the partnership's taxable year.

(e) *Examples.* The following examples illustrate the provisions of this section. In the examples, the partnerships' taxable year is the calendar year 2023 and the partnerships had fewer than 10

returns required to be filed during calendar year 2023:

(1) *Example 1.* Partnership P had five general partners and 90 limited partners on January 1, 2023. On March 15, 2023, 10 more limited partners acquired an interest in P. On September 29, 2023, the 10 newest partners sold their individual partnership interests to C, a corporation which was one of the original 90 limited partners. On December 31, 2023, P had the same five general partners and 90 limited partners it had on January 1, 2023. P had a total of 105 partners over the course of partnership taxable year 2023. Therefore, P must file its 2023 partnership return electronically.

(2) *Example 2.* Partnership Q is a general partnership that had 95 partners on January 1, 2023. On March 15, 2023, 10 partners sold their individual partnership interests to corporation D, which was not previously a partner in Q. On September 29, 2023, corporation D sold one-half of its partnership interest in equal shares to five individuals, who were not previously partners in Q. On December 31, 2023, Q had a total of 91 partners, and on no date in 2023 did Q have more than 100 partners. Over the course of the year, however, Q had 101 partners. Therefore, Q must file its 2023 partnership return electronically.

(3) *Example 3.* Partnership G is a general partnership with 100 partners on January 1, 2023. There are no new partners added to G in 2023. One of G's partners, A, is a partnership with 53 partners. A is one partner, regardless of the number of partners A has. Therefore, G has 100 partners and is not required to file its 2023 partnership return electronically.

(4) *Example 4.* Same facts as paragraph (e)(3) of this section (*Example 3*), except partnership G is also required to file 9 Forms 1099–MISC during calendar year 2023 in addition to its 2022 partnership return. Because partnership G is required to file at least 10 returns of any type during calendar year 2023, partnership G must file its 2023 partnership return electronically.

(f) *Applicability date.* The rules of this section apply for partnership returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 21.** Section 301.6011–5 is amended by revising paragraphs (a), (b), (d)(1) and (5), (e), and (f) to read as follows:

§ 301.6011–5 Required use of electronic form for corporate income tax returns.

(a) *Corporate income tax returns required electronically.* (1) A corporation required to file a corporate income tax return on Form 1120, *U.S. Corporation Income Tax Return,* under § 1.6012–2 of this chapter must file its corporate income tax return electronically if the corporation is required by the Internal Revenue Code or regulations to file at least 10 returns (as defined in paragraph (d)(5) of this section) during the calendar year ending with or within the taxable year of the corporation.

(2) All members of a controlled group of corporations must file their corporate income tax returns electronically if the aggregate number of returns required to be filed by the controlled group of corporations is at least 10 (as defined in paragraph (d)(5) of this section) during the calendar year ending with or within the taxable year of the controlled group of corporations.

(3) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 1.6012–2 of this chapter) and the period to which it applies.

* * * * *

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(5) *Calculating the number of returns.* For purposes of this section, a corporation or controlled group of corporations is required to file at least 10 returns if, during the calendar year ending with or within the taxable year of the corporation or the controlled group, the corporation or the controlled group is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns. In the case of a short-period return, a corporation is required to file at least 10 returns if, during the calendar year in which the corporation's short taxable year ends, the corporation is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns. If the corporation is a member of a controlled group, calculating the number of returns the corporation is required to file includes all returns required to be filed by all members of the controlled group during the calendar year ending with or within the taxable year of the controlled group.

(e) *Example.* The following example illustrates the provisions of this section:

(1) The taxable year of Corporation X, a fiscal-year taxpayer, ends on September 30. During the calendar year ending December 31, 2022, X was required to file one Form 1120, *U.S. Corporation Income Tax Return,* 6 Forms W–2, *Wage and Tax Statement,* 3 Forms 1099–DIV, *Dividends and Distributions,* one Form 940, *Employer's Annual Federal Unemployment (FUTA) Tax Return,* and four Forms 941, *Employer's Quarterly Federal Tax Return.* Because X is required to file 10 returns of any type during calendar year 2022, the calendar year that ended within its taxable year ending September 30, 2023, X is required to file its Form 1120 electronically for its taxable year ending September 30, 2023.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for corporate income tax returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 22.** Section 301.6011–10 is added to read as follows:

§ 301.6011–10 Certain organizations, including trusts, required to file unrelated business income tax returns in electronic form.

(a) *Unrelated business income tax returns required in electronic form.* (1) Organizations, including trusts, subject to tax under section 511 that are required to file a return under § 1.6012–2(e) or 1.6012–3(a)(5) of this chapter to report gross income included in computing unrelated business taxable income, as defined in section 512, or that are otherwise required to file Form 990–T, *Exempt Organization Business Income Tax Return (and proxy tax under section 6033(e)),* are required to file that return in electronic form.

(2) Returns filed in electronic form must be filed in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Failure to file.* If an organization or trust fails to file an unrelated business income tax return in electronic form when required to do so by this section, the organization or trust is deemed to have failed to file the return. (See section 6651 for the addition to tax for failure to file a return.) In determining whether there is reasonable cause for failure to file the return, § 301.6651–1(c) will apply.

(c) *Applicability date.* The rules of this section apply for unrelated business income tax returns required to be filed during calendar years beginning after [the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 23.** Section 301.6011–11 is added to read as follows:

§ 301.6011–11 Required use of electronic form for certain returns for tax-advantaged bonds.

(a) *Return for credit payments to issuers of qualified bonds.* (1) An issuer of a qualified bond required to file a return for credit payments on Form 8038–CP, *Return for Credit Payments to Issuers of Qualified Bonds,* must file its return electronically if the issuer is required to file at least 10 returns (as defined in paragraph (d)(4) of this section) during the calendar year.

(2) Returns filed electronically must be made in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance.

(3) The Commissioner may provide an exemption from the electronic requirements of paragraph (a) of this section through revenue procedures, publications, forms, instructions, or other guidance.

(b) *Other returns for tax-advantaged bonds.* The Commissioner may prescribe by revenue procedure that additional forms for tax-advantaged bonds (as defined in § 1.150–1(b) of this chapter) required under the Internal Revenue Code, regulations, or other administrative guidance published by the Internal Revenue Service must be filed electronically if the issuer is required to file at least 10 returns during the calendar year.

(c) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return for credit payments on Form 8038–CP) and the period to which it applies.

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

(2) *Qualified bond.* The term *qualified bond* means a tax-advantaged bond that is a taxable bond that provides a refundable federal tax credit payable directly to the issuer of the bond under former section 6431 or any other tax-advantaged bond (as defined in § 1.150–1(b) of this chapter) that provides a tax credit payment to issuers of such bonds similar to the credit provided with respect to interest on qualified bonds.

(3) *Return for credit payments to issuers of qualified bonds.* The term *return for credit payments to issuers of qualified bonds* means a Form 8038–CP, *Return for Credit Payments to Issuers of Qualified Bonds* or such other form prescribed by the Commissioner for the purpose of filing a return for credit payment with respect to a qualified bond.

(4) *Calculating the number of returns.* For purposes of this section, an issuer of a tax-advantaged bond is required to file at least 10 returns if, during the calendar year, the issuer is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(e) *Applicability date.* The rules of this section apply for tax-advantaged bond returns required to be filed after the later of December 31, 2021 or [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 24.** Section 301.6011–12 is added to read as follows:

§ 301.6011–12 Required use of electronic form for returns of certain excise taxes under Chapters 41 and 42 of the Internal Revenue Code.

(a) *Excise tax returns required electronically.* (1) Any person required to file an excise tax return on Form 4720, *Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code,* under § 53.6011–1 of this chapter must file its excise tax return electronically if the person is required by the Internal Revenue Code or regulations to file at least 10 returns (as defined in paragraph (d)(3) of this section) during calendar years after 2021.

(2) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(3) Paragraph (a)(1) of this section is not applicable to private foundations that are subject to the filing requirements of § 301.6033–4.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 53.6011–1 of this chapter) and the period to which it applies.

(c) *Failure to file.* If a person fails to file an excise tax return electronically when required to do so by this section, the person is deemed to have failed to

file the return. (See section 6651 for the addition to tax for failure to file a return). In determining whether there is reasonable cause for failure to file the return, § 301.6651–1(c) and rules similar to the rules in § 301.6724–1(c)(3) (undue economic hardship related to filing information returns electronically) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

(2) *Excise tax return.* The term *excise tax return* means a Form 4720, *Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code,* along with all other related forms, schedules, and statements that are required to be attached to the Form 4720, including amended and superseding returns.

(3) *Calculating the number of returns.* For purposes of this section, a person is required to file at least 10 returns if, during the calendar year ending with or within the person's taxable year, the person is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns. In the case of a short-period return, a person is required to file at least 10 returns if, during the calendar year in which the person's short taxable year ends, the person is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(e) *Example.* The following example illustrates the provisions of this section:

(1) During the calendar year ending December 31, 2022, Trust X was required to file one Form 4720, *Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code,* which related to the 2021 taxable year, and 10 Forms W–2, *Wage and Tax Statement,* which reported wages paid to employees during the 2021 taxable year. Because X is required to file 11 returns during calendar year 2022, X is required to file the 2021 Form 4720 electronically.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for excise tax returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 25.** Section 301.6011–13 is added to read as follows:

§ 301.6011–13 Required use of electronic form for split-interest trust returns.

(a) *Split-Interest Trust returns required electronically.* (1) Any trust required to file an information return on Form 5227, *Split-Interest Trust Information Return,* under § 53.6011–1 of this chapter must file its return electronically if the trust is required by the Internal Revenue Code or regulations to file at least 10 returns (as defined in paragraph (d)(3)) of this section) during the calendar year.

(2) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with applicable revenue procedures, publications, forms, or instructions.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 53.6011–1 of this chapter) and the period to which it applies.

(c) *Failure to file.* If a trust fails to file an excise tax return electronically when required to do so by this section, the trust is deemed to have failed to file the return. (See section 6652 for the addition to tax for failure to file a return). In determining whether there is reasonable cause for failure to file the return, § 301.6652–1(f) and rules similar to the rules in § 301.6724–1(c)(3) (undue economic hardship related to filing information returns electronically) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

(2) *Split-Interest Trust return.* The term *split-interest trust return* means a Form 5227, *Split-Interest Trust Information Return,* along with all other related forms, schedules, and statements that are required to be attached to the Form 5227, including amended and superseding returns.

(3) *Calculating the number of returns.* For purposes of this section, a trust is required to file at least 10 returns if, during the calendar year ending with or within the trust's taxable year, the trust is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns. In the case of a short-period return, a trust is required to file at least 10 returns if, during the calendar year in which the trust's short taxable year ends, the trust is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(e) *Example.* The following example illustrates the provisions of this section:

(1) During the calendar year ending December 31, 2022, Trust X was required to file one Form 5227, *Split-Interest Trust Information Return,* one Form 4720, *Return of Certain Excise Taxes Under Chapters 41 and 42 of the Internal Revenue Code,* and 10 Forms 1099–DIV, *Dividends and Distributions.* Because X is required to file 12 returns during the calendar year 2022, X is required to file its Form 5227 electronically for its taxable year ending December 31, 2022.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for Split-Interest Trust returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 26.** Section 301.6011–14 is added to read as follows:

§ 301.6011–14 Required use of electronic form or other machine-readable form for material advisor disclosure statements.

(a) *Material advisor disclosure statements required electronically or in*

other machine-readable form. (1) Any material advisor required to file a return on Form 8918, *Material Advisor Disclosure Statement,* under § 301.6111–3(a) of this chapter must file its return electronically or in other machine-readable form, in accordance with revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website, if the material advisor is required by the Internal Revenue Code or regulations to file at least 10 returns (as defined in paragraph (d)(3)) of this section) during the calendar year.

(2) The Commissioner may direct the type of electronic or other machine-readable form through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically or in other machine-readable form must be made in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 301.6111–3(a) of this chapter) and the period to which it applies.

(c) *Failure to file.* If a material advisor fails to file Form 8918 electronically or in other machine-readable form when required to do so by this section, the material advisor is deemed to have failed to file the return. (See section 6707 for the penalty for failure to file the return.)

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

(2) *Machine-readable form.* The term *machine-readable form* means any machine-readable form specifically permitted under applicable regulations, procedures, publications, forms, instructions, or other guidance.

(3) *Material advisor disclosure statement.* The term *material advisor disclosure statement* means a Form 8918, *Material Advisor Disclosure Statement,* along with all other related forms, schedules, and statements that are required to be attached to the Form 8918, including amended material advisor disclosure statements.

(4) *Calculating the number of returns.* For purposes of this section, a material advisor is required to file at least 10 returns if, during the calendar year ending with or within the material advisor's taxable year, the material advisor is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(e) *Example.* The following example illustrates the provisions of this section:

(1) During the calendar year ending December 31, 2022, Material Advisor X was required to file one Form 8918, *Material Advisor Disclosure Statement,* one Form 1040, *U.S. Individual Income Tax Return,* and 10 Forms 1099–NEC, *Nonemployee Compensation.* Because Material Advisor X is required to file 12 returns during the calendar year 2022, X is required to file its Form 8918 electronically or in other machine-readable form, in accordance with revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website, during its calendar year ending December 31, 2022.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for Material Advisor Disclosure Statements required to be filed for taxable years ending on or after [the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 27.** Section 301.6011–15 is added to read as follows:

§ 301.6011–15 Required use of electronic form for withholding tax returns.

(a) *Withholding tax returns required electronically.* (1) A withholding agent required to file an income tax return on Form 1042, *Annual Withholding Tax Return for U.S. Source Income of Foreign Persons,* under § 1.1461–1 of this chapter must file its return electronically if the withholding agent is required by the Internal Revenue Code or regulations to file at least 10 returns (as defined in paragraph (d)(5) of this section) during the calendar year in which the Form 1042 is required to be filed. Notwithstanding the previous sentence, a withholding agent that is an individual, estate, or trust is not required to file its Form 1042 electronically.

(2) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 1.1461–1 of this chapter) and the period to which it applies.

(c) *Failure to file.* If a withholding agent fails to file a withholding agent income tax return electronically when required to do so by this section, the withholding agent is deemed to have failed to file the return. (See section 6651 for the addition to tax for failure to file a return.) In determining whether there is reasonable cause for failure to file the return, § 301.6651–1(c) and rules similar to the rules in § 301.6724–1(c)(3) (undue economic hardship related to filing information returns electronically) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, and diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, or instructions.

(2) *Withholding agent.* The term *withholding agent* means a withholding agent as defined in § 1.1441–7(a) of this chapter.

(3) *Withholding tax return.* The term *withholding tax return* means a Form

1042, *Annual Withholding Tax Return for U.S. Source Income of Foreign Persons,* along with all other related forms, schedules, and statements that are required to be attached to the Form 1042, including amended and superseding returns.

(4) *Special rule for partnerships.* Notwithstanding paragraph (d)(5) of this section, a withholding agent that is a partnership with more than 100 partners is required to file a return described in paragraph (a) of this section electronically.

(5) *Calculating the number of returns.* For purposes of this section, a withholding agent is required to file at least 10 returns if, during the calendar year in which the Form 1042 is required to be filed, the withholding agent is required to file at least 10 returns of any type, including information returns (for example, Forms W–2, Forms 1099, Forms 1042–S), income tax returns (for example, Form 1042), employment tax returns, and excise tax returns.

(e) *Special rule for returns filed by financial institutions.* For rules that require withholding agents that are financial institutions to file returns electronically, see § 301.1474–1.

(f) *Applicability date.* The rules of this section apply to withholding tax returns required to be filed for taxable years ending on or after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 28.** Section 301.6012–2 is added to read as follows:

§ 301.6012–2 Required use of electronic form for income tax returns of certain political organizations.

(a) *Income tax returns of certain political organizations required electronically.* (1) Any organization required to file an income tax return on Form 1120–POL, *U.S. Income Tax Return for Certain Political Organizations,* under § 1.6012–6 of this chapter must file its income tax return, along with all other related forms, schedules, and statements that are required to be attached to the Form 1120–POL, including amended and superseding returns, electronically if the organization is required by the Internal Revenue Code or regulations to file at least 10 returns of any type (as defined in paragraph (d)(2)) during the calendar year.

(2) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under § 1.6012–6 of this chapter) and the period to which it applies.

(c) *Failure to file.* If an organization fails to file an income tax return electronically when required to do so by this section, the organization is deemed to have failed to file the return. (See section 6651 for the addition to tax for failure to file a return.) In determining whether there is reasonable cause for failure to file the return, § 301.6651–1(c) and rules similar to the rules in § 301.6724–1(c)(3) (undue economic hardship related to filing information returns electronically) will apply.

(d) *Meaning of terms.* The following definitions apply for purposes of this section:

(1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

(2) *Income tax return for certain political organizations.* The term *income tax return for certain political organizations* means a Form 1120–POL, *U.S. Income Tax Return for Certain Political Organizations,* along with all other related forms, schedules, and statements that are required to be attached to the Form 1120–POL, including amended and superseding returns.

(3) *Calculating the number of returns.* For purposes of this section, an organization is required to file at least 10 returns if, during the calendar year ending with or within the organization's taxable year, the organization is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns. In the case of a short-period return, an organization is required to file at least 10 returns if, during the calendar year in which the organization's short taxable year ends, the organization is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

(e) *Example.* The following example illustrates the provisions of this section:

(1) During the calendar year ending December 31, 2022, Organization X was required to file one Form 1120–POL, *U.S. Income Tax Return for Certain Political Organizations,* four (quarterly) Forms 8872, *Political Organization Report of Contributions and Expenditures,* two Forms W–2, *Wage and Tax Statement,* one Form 940, *Employer's Annual Federal Unemployment (FUTA) Tax Return,* and four Forms 941, *Employer's Quarterly Federal Tax Return.* Because X is required to file 12 returns during the calendar year, X is required to file its Form 1120–POL electronically for its taxable year ending December 31, 2022.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for income tax returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 29.** Section 301.6033–4 is revised to read as follows:

§ 301.6033–4 Required filing in electronic form for returns by organizations required to file returns under section 6033.

(a) *Returns by organizations required to file returns under section 6033 in electronic form.* (1) An organization required to file a return under section 6033 must file its return in electronic form.

(2) Returns filed in electronic form must be filed in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Failure to file.* If an organization required to file a return under section 6033 fails to file an information return in electronic form when required to do so by this section, the organization is deemed to have failed to file the return. (See section 6652 for the addition to tax for failure to file a return.) In determining whether there is reasonable cause for failure to file the return, § 301.6652–2(f) will apply.

(c) *Meaning of terms.* For purposes of this section the term *return required under section 6033* means a Form 990, *Return of Organization Exempt From Income Tax,* Form 990–EZ, *Short Form Return of Organization Exempt From Income Tax,* and Form 990–PF, *Return of Private Foundation or Section 4947(a)(1) Trust Treated as Private Foundation,* along with all other related forms, schedules, and statements that are required to be attached to the Form 990, Form 990–EZ, or Form 990–PF, and all members of the Form 990 series of returns, including amended and superseding returns. A Form 4720 filed by a private foundation is a form required to be filed under section 6033.

(d) *Applicability date.* The rules of this section apply for any returns under section 6033 required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 30.** Section 301.6037–2 is amended by revising the section heading, paragraphs (a), (b), (d)(1) and (5), (e) and (f) to read as follows:

§ 301.6037–2 Required use of electronic form for returns of electing small business corporation.

(a) *Returns of electing small business corporation required electronically.* (1) An electing small business corporation required to file an electing small business return on Form 1120–S, *U.S. Income Tax Return for an S Corporation,* under § 1.6037–1 of this chapter must file its Form 1120–S electronically if the small business corporation is required by the Internal Revenue Code and regulations to file at least 10 returns during the calendar year.

(2) The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may grant waivers of the requirements of this section in cases of undue hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the return on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under section 6037) and the period to which it applies.

* * * * *

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(5) *Calculating the number of returns.* For purposes of this section, a corporation is required to file at least 10 returns if, during the calendar year ending with or within the corporation's taxable year, the corporation is required to file at least 10 returns of any type, including income tax returns, employment tax returns, excise tax returns, and information returns (for example, Forms W–2, Forms 1099, but not including schedules required to be attached to an S corporation return). In the case of a short-period return, a corporation is required to file at least 10 returns if, during the calendar year in which the corporation's short taxable year ends, the corporation is required to file at least 10 returns of any type, including information returns (for example, Forms W–2, Forms 1099, but not including schedules required to be attached to an S corporation return), income tax returns, employment tax returns, and excise tax returns.

(e) *Example.* The following example illustrates the provisions of this section. In the example, the corporation is a calendar-year taxpayer.

(1) In 2022, Corporation S, an electing small business corporation, is required to file one 2021 Form 1120–S, *U.S. Corporation Income Tax Return,* two Forms W–2, *Wage and Tax Statement,* two Forms 1099–DIV, *Dividends and Distributions,* one Form 940, *Employer's Annual Federal Unemployment (FUTA) Tax Return,* and four Forms 941, *Employer's Quarterly Federal Tax Return.* Because S is required to file 10 returns during the calendar year 2022, S is required to file its 2022 Form 1120–S electronically.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for electing small business corporation returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**].

■ **Par. 31.** Section 301.6057–3 is amended by:

■ 1. Revising paragraphs (a), (b), and (d)(1);

■ 2. Revising the heading of paragraph (d)(4);

■ 3. Revising paragraph (d)(4)(i);

■ 4. In paragraph (e), designating the example as paragraph (e)(1).

■ 5. Revising newly designated paragraph (e)(1) and adding paragraph (e)(2); and

■ 6. Revising paragraph (f).

The revisions and addition read as follows:

§ 301.6057–3 Required use of electronic form for filing requirements relating to deferred vested retirement benefit.

(a) *Electronic-filing requirements under section 6057.* A registration statement required under section 6057(a) or a notification required under section 6057(b) with respect to an employee benefit plan must be filed electronically if the filer is required by the Internal Revenue Code or regulations to file at least 10 returns during the calendar year that includes the first day of the plan year. The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may waive the requirements of this section in cases of undue economic hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the registration statements or notifications electronically in accordance with this section exceeds the cost of filing the registration statements or notifications on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a registration statement or notification under section 6057) and the period to which it applies.

* * * * *

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(4) *Calculating the number of returns*—(i) *In general.* For purposes of this section, a filer is required to file at least 10 returns if, during the calendar year that includes the first day of the plan year, the filer is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

* * * * *

(e) * * *

(1) *Example.* In 2023, P, the plan administrator of Plan B, is required to file 12 returns (including Forms 1099–R, *Distributions From Pensions, Annuities, Retirement or Profit-Sharing Plans, IRAs, Insurance Contracts, etc.;* Form 8955–SSA; Form 5500, *Annual Return/Report of Employee Benefit Plan;* and Form 945, *Annual Return of Withheld Federal Income Tax*). Plan B's plan year is the calendar year. Because P is required to file at least 10 returns during the 2023 calendar year, P must file the 2023 Form 8955–SSA for Plan B electronically.

(2) [Reserved]

(f) *Applicability date.* The rules of this section apply for registration statements and other notifications required to be filed under section 6057 for plan years that begin on or after January 1, 2022, but only for filings with a filing deadline (not taking into account extensions) after July 31, 2022.

■ **Par. 32.** Section 301.6058–2 is amended by:

■ 1. Revising the section heading.

■ 2. Revising paragraphs (a), (b), and (d)(1);

■ 3. Revising the heading of paragraph (d)(3); and

■ 4. Revising paragraphs (d)(3)(i), (d)(3)(iii), (e), and (f).

The revisions read as follows:

§ 301.6058–2 Required use of electronic form for filing requirements relating to information required in connection with certain plans of deferred compensation.

(a) *Electronic-filing requirements under section 6058.* A return required under section 6058 with respect to an employee benefit plan must be filed electronically if the filer is required by the Internal Revenue Code or regulations to file at least 10 returns during the calendar year that includes the first day of the plan year. The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Returns filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may waive the requirements of this section in cases of undue economic hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the return electronically in accordance with this section exceeds the cost of filing the returns on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, a return required under section 6058) and the period to which it applies.

* * * * *

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(3) *Calculating the number of returns*—(i) *In general.* For purposes of this section, a filer is required to file at least 10 returns if, during the calendar year that includes the first day of the plan year, the filer is required to file at least 10 returns of any type, including information returns (for example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns. See section 6011(e)(6), Application of numerical limitation to returns relating to deferred compensation plans.

* * * * *

(iii) *Special rules relating to calculating the number of returns.* For purposes of applying paragraph (d)(3)(ii) of this section, the aggregation rules of section 414(b), (c), (m), and (o) will apply to a filer that is or includes an employer. Thus, for example, a filer that is a member of a controlled group of corporations within the meaning of section 414(b) must file the Form 5500 series electronically if the aggregate number of returns required to be filed by all members of the controlled group of corporations is at least 10 returns.

(e) *Example.* The following example illustrates the provisions of paragraph (d)(3) of this section:

(1) In 2023, Employer X (the plan sponsor and plan administrator of Plan A) is required to file 12 returns. The sole shareholder of X and his spouse are the only participants in Plan A. Employer X is required to file the following: One Form 1120, *U.S. Corporation Income Tax Return;* two Forms W–2, *Wage and Tax Statement;* one Form 940, *Employer's Annual Federal Unemployment (FUTA) Tax Return;* four Forms 941, *Employer's Quarterly Federal Tax Return;* one Form 945, *Annual Return of Withheld Federal Income Tax;* and two Forms 1099–DIV, *Dividends and Distributions.* Employer X is required to file one Form 5500–EZ. Plan A's plan year is the calendar year. Because Employer X is required to file at least 10 returns during the 2023 calendar year, the 2023 Form 5500–EZ must be filed electronically.

(2) [Reserved]

(f) *Applicability date.* This section is applicable for returns required to be filed under section 6058 for plan years that begin on or after January 1, 2022, but only for filings with a filing deadline (not taking into account extensions) after July 31, 2022.

■ **Par. 33.** Section 301.6059–2 is amended by:

■ 1. Revising the section heading;

■ 2. Revising paragraphs (a), (b), (d)(1);

■ 3. In paragraph (d)(3), revising the paragraph heading and paragraph (d)(3)(i);

■ 4. Removing paragraph (e) and redesignating paragraph (f) as paragraph (e); and

■ 5. Revising newly designated paragraph (e).

The revisions read as follows:

§ 301.6059–2 Required use of electronic form for filing requirements relating to periodic report of actuary.

(a) *Electronic-filing requirements under section 6059.* An actuarial report required under section 6059 with respect to an employee benefit plan must be filed electronically if the filer is required by the Internal Revenue Code or regulations to file at least 10 returns during the calendar year that includes the first day of the plan year.

The Commissioner may direct the type of electronic filing and may also exempt certain returns from the electronic requirements of this section through revenue procedures, publications, forms, instructions, or other guidance, including postings on the *IRS.gov* website. Actuarial reports filed electronically must be made in accordance with the applicable revenue procedures, publications, forms, instructions, or other guidance.

(b) *Undue hardship.* The Commissioner may waive the requirements of this section in cases of undue economic hardship. The principal factor in determining hardship will be the amount, if any, by which the cost of filing the reports electronically in accordance with this section exceeds the cost of filing the reports on paper. A request for a waiver must be made in accordance with applicable IRS revenue procedures, publications, forms, instructions, or other guidance, including postings to the *IRS.gov* website. The waiver will specify the type of filing (that is, an actuarial report required under section 6059) and the period to which it applies.

* * * * *

(d) * * * (1) *Magnetic media or electronic form.* The terms *magnetic media or electronic form* mean any media or form permitted under applicable regulations, revenue procedures, or publications. These generally include electronic filing, as well as magnetic tape, tape cartridge, diskette, and other media specifically permitted under the applicable regulations, procedures, publications, forms, instructions, or other guidance.

* * * * *

(3) *Calculating the number of returns*—(i) *In general.* For purposes of this section, a filer is required to file at least 10 returns if, during the calendar year that includes the first day of the plan year, the filer is required to file at least 10 returns of any type, including information returns (or example, Forms W–2 and Forms 1099), income tax returns, employment tax returns, and excise tax returns.

* * * * *

(e) *Applicability date.* This section is applicable for actuarial reports required to be filed under section 6059 for plan years that begin on or after January 1, 2022, but only for filings with a filing deadline (not taking into account extensions) after July 31, 2022.

■ **Par. 34.** Section 301.6721–1 is amended by:

■ 1. Revising paragraph (a)(2)(ii).

■ 2. In paragraph (b)(5), revising the introductory text.

■ 3. In paragraph (b)(5), designating *Examples 1* through *4* as paragraphs (b)(5)(i) through (iv).

■ 4. Revising newly designated paragraphs (b)(5)(iii) and (b)(5)(iv).

■ 5. Adding paragraphs (b)(5)(v) and (b)(5)(vi).

■ 6. Adding paragraph (h).

The revisions and additions read as follows:

§ 301.6721–1 Failure to file correct information returns.

(a) * * *

(2) * * *

(ii) A failure to include all the information required to be shown on the return or including incorrect information (failure to include correct information). A failure to file timely includes a failure to file in the required manner, for example, electronically or in other machine-readable form as provided under section 6011(e). However, no penalty is imposed under paragraph (a)(1) of this section solely by reason of any failure to comply with the requirements of section 6011(e)(2), except to the extent that the failure occurs with respect to more than the applicable number of returns (determined under regulations prescribed under section 6011(e)(5) with respect to the calendar year during which such returns are required to be filed), or with respect to a return described in section 6011(e)(4). If a partnership return under section 6031(a) is required to be filed electronically, each schedule required to be included with such return with respect to each partner will be treated as a separate information return for purposes of this section. See section 6724(e). Filers who are required to file information returns electronically and who file those information returns electronically are considered to have satisfied the electronic filing requirement. Except as provided in paragraph (c)(1) or (e)(1) of this section, a failure to include correct information encompasses a failure to include the information required by applicable information-reporting statutes or by any administrative pronouncements issued thereunder (such as regulations, revenue rulings, revenue procedures, or information-reporting forms, and form instructions). A failure to include information in the correct format may be either a failure to file timely an information return or a failure to include correct information on an information return. For example, an error on an electronic submission to the Internal Revenue Service that prevents processing by the Internal Revenue Service may constitute a failure to file timely. However, if information is set forth on the wrong field of the electronic submission, that error may constitute a failure to file timely or a failure to include correct information, depending upon the extent of the failure. For purposes of paragraph (b) of this section, a failure to file corrected information returns in the format required under § 301.6011–2(c)(4)(ii) will be deemed a failure to correct the corresponding original information returns.

(b) * * *

(5) *Examples.* The provisions of paragraphs (a) and (b)(1) through (4) of this section may be illustrated by the following examples. These examples do not take into account any possible application of the *de minimis* exception under paragraph (d) of this section, the lower small business limitations under paragraph (e) of this section, the penalty for intentional disregard under paragraph (f) of this section, adjustments for inflation under section 6721(f), or the reasonable-cause waiver under § 301.6724–1(a):

* * * * *

(iii) *Example 3.* In calendar year 2023, Corporation U timely files on paper 12 Forms 1099–MISC for the 2022 calendar year with correct information. Under § 301.6011–2, a person required to file at least 10 returns during calendar year 2023 must file those returns electronically. Corporation U does not correct its failures to file these returns electronically by August 1, 2023. See section 6721(b)(2). Corporation U is therefore subject to a penalty for a failure to file timely under paragraph (a)(2) of this section. However, under section 6724(c) and paragraph (a)(2) of this section, the penalty for a failure to file timely electronically applies only to the extent the number of returns exceeds 10. As Corporation U was required to file 12 returns electronically, it is subject to a penalty of $500 for 2 returns ($250 × 2 = $500).

(iv) *Example 4.* In calendar year 2023, Corporation W timely electronically files 25 Forms 1099–B (relating to proceeds from broker and barter exchange transactions) with incorrect information. On August 1, 2023, Corporation W discovers the errors and files 25 corrected Forms 1099–B on paper. Under § 301.6011–2(c)(4)(2)(A), a person required to file an original information return covered by § 301.6011–2(b) electronically must file any corrected information return corresponding to that original return electronically. Under paragraph (a)(2)(ii) of this section, a failure to file a corrected information return electronically when required to do so is

deemed a failure to correct the corresponding original information return. As Corporation W was required to file its 25 corrected information returns electronically, it is deemed to have failed to correct the original information returns and is subject to a penalty of $6,250 for failure to include correct information on its 25 original Forms 1099–B ($250 × 25 = $6,250), without any reductions for correcting the information on or before August 1.

(v) *Example 5.* During the 2023 calendar year, Corporation V files 25 Forms 1099–B (relating to proceeds from broker and barter exchange transactions) on paper. The forms were filed on March 15, 2023, rather than on the required filing date of February 28, 2023. Under § 301.6011–2, a person required to file at least 10 returns during calendar years 2023 and after must file those returns electronically. Corporation V does not correctly file these returns electronically by August 1, 2023. See section 6721(b)(2). Corporation V is subject to a penalty of $500 for filing 10 of the returns late, but within 30 days after the required filing date ($50 × 10). In addition, Corporation V is subject to a penalty of $3,750 for failing to file 15 returns electronically ($250 × 15).

(vi) *Example 6.* Partnership X has 120 partners in calendar year 2022. In calendar year 2023, it timely filed on paper its 2022 Form 1065 and 230 accompanying Schedules K–1 and Schedules K–3 (120 Schedules K–1 and 110 Schedules K–3). Partnership X filed no other returns during calendar year 2023. Under § 301.6011–3(a)(1)(B), a partnership with more than 100 partners must electronically file its partnership return, including Schedules K–1 and K–3. Under section 6724(e), Schedules K–1 and K–3 are treated as separate information returns for purposes of penalties under section 6721, even though they are not listed under § 301.6011–2(b) as information returns required to be filed electronically and are not defined as information returns under section 6724(d). Because the applicable number for information returns required to be filed during calendar year 2023 is 10, Partnership X would be subject to a penalty of $55,000 for failing to electronically file 220 Schedules K–1 and K–3 required to be included with the partnership return: The 11th through the 230th of the required schedules ($250 × 220 = $55,000).

* * * * *

(h) *Applicability date.* The rules of paragraph (a)(2)(ii) of this section apply for information returns required to be filed during calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**]. For the rules that apply under paragraph (a)(2)(ii) of this section for information returns required to be filed before calendar years beginning after [Date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**], see 26 CFR part 301, revised as of April 1, 2021.

Douglas W. O'Donnell,

Deputy Commissioner for Services and Enforcement.

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